

EXHIBIT 3

1 WILLIAM J. VIGILANTE, JR.
 2 IN THE UNITED STATES DISTRICT COURT FOR THE
 3 WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION
 4 - - -
 5 GARY BRYAN BRACKIN, :
 individually and in his :
 6 capacity as Surviving :
 Spouse of PAMELA W. BRACKIN, :
 7 Deceased, :
 Plaintiff, :
 8 :
 vs. :
 9 :
 MEDTRONIC, INC., et al., :
 10 Defendants. : No. 2:17-cv-2101

11 - - -
 12 September 14, 2018

13 - - -
 14 Videotape deposition of WILLIAM J.
 15 VIGILANTE, JR. taken pursuant to notice held at
 16 the Law Offices of Williams Cedar, LLC, 1515
 17 Market Street, Suite 1300, Philadelphia,
 18 Pennsylvania 19102, commencing at 10:07 a.m.,
 19 on the above date, before Jennifer P. Miller,
 20 RPR, CCR, CRR #30XI00235100 and Notary Public.

21
 22
 23
 24
 25

Job Number: 147847

Page 2

1 WILLIAM J. VIGILANTE, JR.
 2 A P P E A R A N C E S:
 3 KEVIN HAVERTY, ESQUIRE
 4 WILLIAMS CEDAR
 5 8 Kings Highway West
 6 Haddonfield, NJ 08033
 7 Counsel for Plaintiff

11 CLIFF MERRELL, ESQUIRE
 12 GREENBERG TRAURIG
 13 Terminus 200
 14 333 Piedmont Road, NE
 15 Atlanta, GA 30305
 16 Counsel for Defendants

20 ALSO PRESENT: Dan Dickerson, Videographer

Page 3

1 WILLIAM J. VIGILANTE, JR.
 2 THE VIDEOGRAPHER: This is the
 3 start of DVD number one of the video
 4 recorded deposition of William Vigilante
 5 in the matter of Gary Bryan Brackin, et
 6 al. versus Medtronic, Inc., et al. in the
 7 United States District Court for the
 8 Western District of Tennessee, Western
 9 Division, the docket number is
 10 217-CV-2101.

11 This deposition is being held at
 12 William Cedar, LLC in Philadelphia on
 13 9/14/18 at approximately 10:07. My name
 14 is Dan Dickerson. I'm the Legal
 15 Videographer Specialist from TSG
 16 Reporting. The Court Reporter is Jennifer
 17 Billstein-Miller in association with TSG
 18 Reporting. Will counsel please introduce
 19 yourselves.

20 MR. HAVERTY: Good morning.
 21 Kevin Haverty, William Cedar, for the
 22 Plaintiff.

23 MR. MERRELL: Cliff Merrell on
 24 behalf of Defendants Medtronic, Inc. and
 25 Medtronic MiniMed, Inc.

Page 4

1 WILLIAM J. VIGILANTE, JR.
 2 THE VIDEOGRAPHER: Will the
 3 Court Reporter please swear in the
 4 witness.

5 - - -

6 WILLIAM J. VIGILANTE, JR.,
 7 after having been first duly sworn,
 8 was examined and testified as follows:

9 - - -

10 E X A M I N A T I O N

11 - - -

12 BY MR. MERRELL:

13 Q. Good morning, Dr. Vigilante. How are
 14 you?

15 A. Good. Good morning.

16 Q. We met off the record. I just wanted
 17 to ask a few preliminary questions: First, I
 18 understand you've had your deposition taken in
 19 the past, correct?

20 A. I have.

21 Q. About how many times have you been
 22 deposed in the deposition?

23 A. Over 150 times.

24 Q. And how many times have you testified
 25 at trial?

Page 5

1 WILLIAM J. VIGILANTE, JR.

2 A. I think over 40.

3 Q. Okay. So I can probably dispense and
 4 skip most of the preliminary things I might do
 5 in a deposition. But you understand if you
 6 don't understand my question, just ask me to
 7 repeat it or rephrase it; does that make sense?

8 A. Yes.

9 Q. And if at any time you need a break,
 10 obviously, let me know and we can take a break
 11 at any time.

12 A. Okay.

13 Q. What did you do to prepare for your
 14 deposition today?

15 A. Multiple things.

16 Q. And what were those things?

17 A. I put together the -- I think you
 18 guys requested documents in the Notice of
 19 Deposition, so I put that together. I reviewed
 20 my file. I spoke to my client, Mr. Haverty.

21 I think that's generally it.

22 MR. MERRELL: Okay. I'm going
 23 to go ahead and mark as Exhibit 1 the
 24 Notice of Videotape Deposition and hand a
 25 copy of that to you.

Page 6

1 WILLIAM J. VIGILANTE, JR.

2 - - -

3 (Whereupon, Exhibit 1 was
4 marked for identification.)

5 - - -

6 BY MR. MERRELL:

7 Q. I should have a copy of everything,
8 Mr. Vigilante. But if I don't I'll let you
9 know, Mr. Haverty.

10 And this document, Exhibit 1, is
11 the Notice of Videotape Deposition. I believe
12 you just referenced it. Is this a document you
13 reviewed in preparation for your deposition?

14 A. Yes.

15 Q. Okay. And there are a number of
16 document requests beginning on page six; do you
17 see that?

18 A. Yes.

19 Q. And they're itemized one through 26
20 with various letter subparts; do you see that?

21 A. Yes.

22 Q. And have you endeavored to collect
23 and bring with you today the materials
24 requested in the deposition notice?

25 A. Yes.

Page 7

1 WILLIAM J. VIGILANTE, JR.

2 Q. And what have you brought with you
3 today?

4 A. I brought a disc that contains the
5 responses for -- from the -- the notice.

6 Q. Anything in addition to the disc?

7 A. I brought a copy of everything that's
8 on the disc except for the medical records on
9 my laptop.

10 Q. Okay. And I have a, which I'll mark
11 in a moment, I have a thumb drive of materials
12 that were provided to us along with your expert
13 report.

14 Do you know whether or not the
15 materials you were provided, the date your
16 report was issued on July 31st, 2018, are those
17 the same materials that are on the disc, or do
18 you think there are some materials on the disc
19 in addition to that?

20 A. I'm not sure what's on the thumb
21 drive, but I'm going to guess that there's
22 additional documents on the disc.

23 Q. Do you know whether or not that
24 you've been provided with any documents or
25 depositions following the issuance of your

Page 8

1 WILLIAM J. VIGILANTE, JR.
2 expert report on July 31st, 2018?

3 A. Yes.

4 Q. And what depositions or documents do
5 you believe you've been provided since then?

6 A. I know I received the deposition of a
7 Luci Brackin, a Kristin Bettis and a Rita
8 Weaver.

9 Q. Have you been provided any other
10 depositions or documents you see there on your
11 laptop?

12 A. The only one that's -- may not be on
13 the USB drive that's on here is the deposition
14 of I believe Antatoly Aleksandrovich. I
15 initially had that deposition and then somehow
16 or another I lost it in the file and I was sent
17 another copy of it recently.

18 Q. Okay. Any other documents or
19 depositions you can think of that you have
20 received since July 31st, 2018?

21 A. I believe I received the affidavit of
22 Jane Hartley after writing -- after drafting my
23 report.

24 Q. Okay. Anything else you can think of
25 that you received since July 31st, 2018?

Page 9

1 WILLIAM J. VIGILANTE, JR.

2 A. Not that I can recall.

3 Q. Now, you mentioned several -- several
4 depositions and I want to start with each one.
5 The Luci Brackin deposition, have you reviewed
6 that deposition since receiving it?

7 A. Yes.

8 Q. The Kristin Bettis deposition, have
9 you reviewed that deposition?

10 A. Yes.

11 Q. And the Rita Weaver Goidel, have you
12 read her deposition as well?

13 A. Yes.

14 MR. MERRELL: I'm going to mark
15 as Exhibit 2 a copy of the CD. If you
16 just hand it to me, I'll get a copy made
17 of this for part of the exhibits. During
18 the break, I'll see if I can access it,
19 although I don't have a CD drive.

20 Not everyone has switched to
21 thumb drives, Kevin.

22 - - -

23 (Whereupon, Exhibit 2 was
24 marked for identification.)

25 - - -

Page 10

1 WILLIAM J. VIGILANTE, JR.
2 BY MR. MERRELL:

3 Q. You mentioned your preparation for
4 the deposition. A couple of follow-up
5 questions about the notice.

6 We have a copy of your CV from
7 your expert report on July 31st. Has your CV
8 been updated at all since then?

9 A. Do you have a date on the CV?

10 MR. MERRELL: Why don't we go
11 ahead and mark it as an exhibit. Mark as
12 Exhibit 3 a copy of the Curriculum Vitae
13 we have for Dr. Vigilante.

14 - - -

15 (Whereupon, Exhibit 3 was
16 marked for identification.)

17 - - -

18 BY MR. MERRELL:

19 Q. I'll hand that to you. It appears to
20 be dated February 25th, 2018.

21 Do you have any more up-to-date
22 CV than the one that's been provided here?

23 A. That's my current CV.

24 Q. Have you brought with you any
25 invoices or billing materials at all?

Page 11

1 WILLIAM J. VIGILANTE, JR.

2 A. I did.

3 Q. You said yes?

4 A. Yes.

5 Q. And are those on a CD or are they
6 hard copy?

7 A. I brought a copy on the CD. I
8 brought a copy on my computer.

9 Q. Okay. And would you be able to
10 access a copy of those billing records if I
11 need to ask you questions later?

12 A. Sure.

13 Q. Okay. Outside of the CD you
14 provided, are there any other materials that
15 you've relied upon or reviewed in coming to
16 your opinions in this case?

17 A. Yes.

18 Q. What would those be?

19 A. Number one off the top of my head is
20 my experience during my investigation of the
21 Dennert matter, Rachel Dennert matter; number
22 two, my general education, training and
23 background with respect to human factors,
24 product design and to design an assessment of
25 product warnings and instructions.

Page 12

1 WILLIAM J. VIGILANTE, JR.

2 Q. Anything else you can think of, the
3 documents or literature or guidances?

4 A. Not offhand.

5 Q. You do have a number of references in
6 your report, which we'll get to later in the
7 deposition, of guidances and literature. Are
8 those on the CD you provided as Exhibit 2 today
9 as well?

10 A. Yes.

11 Q. Is there any other literature or
12 guidances or other documents you relied upon in
13 coming to your opinions outside of those that
14 are referenced in your CV -- I'm sorry, those
15 that are referenced in your report and those
16 that are on the CD Exhibit No. 2?

17 A. I'm not sure I understand what you're
18 asking me.

19 Q. Okay. I'll try to ask it a different
20 way.

21 Are you -- are you relying upon
22 any other literature or guidances at all in
23 coming to your opinions here that would not
24 appear on your expert report or on the CD you
25 provided today which we marked as Exhibit 2?

Page 13

1 WILLIAM J. VIGILANTE, JR.

2 A. I think the only other specific
3 reference that I included in the CD was the
4 2016 version of the FDA's medical applying
5 human factors and usability engineering to
6 medical devices. I think that's the only other
7 specific references -- reference that I
8 included that's not noted in my report.

9 Q. Okay. And we'll get to this later.

10 But in your report, the guidance you relied
11 upon, was it the 2000 version for human factors
12 that the FDA issued?

13 A. I believe it's 2000.

14 Q. Did you --

15 A. Yes, I'm sorry.

16 Q. I'm sorry, I didn't mean to cut you
17 off.

18 A. It's okay.

19 Q. Was it the 2000?

20 A. Yes.

21 Q. Did you -- and you since provided the
22 2016 guidance, are you relying upon that in any
23 respect in coming to your opinions here?

24 A. Not necessarily.

25 Q. Have you conducted any sort of

1 WILLIAM J. VIGILANTE, JR.
 2 testing or experimentation at all in this case
 3 to come to your opinions?
 4 A. I did.
 5 Q. What sort of testing experimentation
 6 did you conduct?
 7 A. I tested my opinions.
 8 Q. And how did you do that?
 9 A. What I did was, I started with
 10 essentially applying the scientific method to
 11 the different questions I was asked to address.
 12 So after talking with Mr. Haverty, we agreed on
 13 certain areas that I would look into.

14 I had done preliminary research,
 15 again, based upon my prior experience in the
 16 matter. Using that and some other preliminary
 17 investigation I created, I came up with three
 18 questions that I wanted to address. They are
 19 listed in my report. The first is whether or
 20 not Medtronic conducted an adequate human
 21 factors analysis of its product and whether its
 22 failure to do so caused or contributed to
 23 Pamela Brackin's injury and death; whether
 24 Medtronic provided adequate instructions and
 25 warnings with its Paradigm reservoir and

1 WILLIAM J. VIGILANTE, JR.
 2 infusion set regarding the hazard associated
 3 with the potential lockage of the P-Cap
 4 connector vent. And then the last hypothesis
 5 was whether Medtronic, whether their failure to
 6 provide adequate instructions and warnings
 7 regarding the hazard associated with the
 8 potential blockage of its P-Cap connector vent
 9 was improper in the manner which caused or
 10 contributed to Ms. Brackin's injury and death.

11 So for the first, I looked at
 12 whether or not there was a hazard associated
 13 with the use -- foreseeable use, I should say,
 14 of the P-Cap connector, the infusion set, the
 15 reservoir, et cetera. Based upon information
 16 from discovery information provided in the
 17 case, specifically Randy Adair and some of the
 18 other information that was produced, I
 19 concluded that there was, in fact, a hazard
 20 associated with the unattended delivery of
 21 insulin resulting from the blockage of P-Cap
 22 connector vents.

23 The second thing I looked at is
 24 whether Medtronic conducted a proper risk and
 25 human factors analysis. So one of the first

1 WILLIAM J. VIGILANTE, JR.
 2 things I did was I looked at the standard of
 3 care for both product design, development and
 4 the design development of medical devices to
 5 see what was the standard of care for product
 6 designers such as Medtronic and designing and
 7 developing a product such as the P-Cap
 8 connector, the reservoir and -- and the
 9 infusion set.

10 So I lay out those specific
 11 steps and specific requirements in my report
 12 under section E2. Then using the discovery
 13 material provided in the case, I looked at what
 14 Medtronic had done both when they were
 15 developing the product in the 1990s, late '90s,
 16 early 2000s and up to Mrs. Brackin's event, and
 17 compared them, tested them against the standard
 18 of care, and found that they were, in fact,
 19 deficient. Again, that's noted through section
 20 E2 in my report.

21 Based upon my testing of my
 22 apotheosis, I came to my opinions with respect
 23 to that topic. I then looked at questions
 24 related to -- issues related to failure to warn
 25 and instructions. Again, that's laid out in

1 WILLIAM J. VIGILANTE, JR.
 2 section E3 in my report.

3 What I looked at again was the
 4 standard of care for the design and development
 5 of warnings and instructional material. I
 6 looked at the information provided by
 7 Medtronic, both pre and post-2013, including
 8 the Getting Started Guide that was relied upon
 9 by the Brackins in using the -- using the
 10 product.

11 I tested what Medtronic had done
 12 based upon their records, deposition testimony,
 13 to the standard of care, and came to my
 14 opinions with respect to that topic.

15 I then looked to see whether or
 16 not adequate instructions and warnings could
 17 have and should have been designed in
 18 development, and I addressed that in section E4
 19 in my report. To do that, I looked at what the
 20 standard of care was for the design and
 21 development again of warnings and instructions,
 22 and developed an alternative warning and
 23 instructions set based upon those standards,
 24 guidelines and recommendations, and then came
 25 to my conclusions with respect to that topic.

1 WILLIAM J. VIGILANTE, JR.

2 Q. Okay. And that information you just
3 provided in your testimony, is that all
4 included in your expert report?

5 A. Yes.

6 Q. Have you ever handled a Medtronic 523
7 insulin pump?

8 A. I don't know if I handled the 523
9 insulin pump, but I handled a similar insulin
10 pump in my investigation of the Dennert matter.
11 And I don't recall exactly which model number
12 it was, but it was a similar pump.

13 Q. Since handling the insulin pump
14 involved in the Dennert case, have you handled
15 another insulin pump at all?

16 A. I have not.

17 Q. Have you handled the reservoir at
18 issue in this case?

19 A. The specific reservoir issue in this
20 case, I was not provided with.

21 Q. Have you handled the specific
22 infusion set at issue in this case?

23 A. I have not. I'm not aware of them
24 being available.

25 Q. All right. And I'll probably ask

1 WILLIAM J. VIGILANTE, JR.

2 another question. Have you handled an exemplar
3 of the reservoir at issue in this case?

4 A. I have examined an exemplar of the
5 reservoir infusion set. I don't know that they
6 were the specific batch or model number of the
7 one used by Mrs. Brackin.

8 Q. And when did you -- when did you do
9 that?

10 A. Through my investigation of the
11 Dennert matter.

12 Q. So since the Dennert matter, have you
13 handled an insulin pump infusion set or
14 reservoir?

15 A. I have not.

16 Q. In this specific case, did you
17 conduct any sort of experimentation with an
18 insulin pump or reservoir or infusion set -- I
19 assume not since you haven't handled them since
20 then?

21 A. The only experimentation I do is look
22 through the user guides, Getting Started Guides
23 and IFUs to understand how they worked to
24 ensure that they were similar to my experiences
25 in the Dennert case.

1 WILLIAM J. VIGILANTE, JR.

2 Q. Okay. And when you went through
3 those, I take it, though, in this particular
4 case you didn't utilize an insulin pump,
5 reservoir, infusion set?

6 A. I did not physically interact with or
7 handle a reservoir, infusion set or pump in my
8 investigation of this case. I relied upon my
9 experience in the Dennert matter.

10 I need to append that answer.
11 Also, I relied upon my review of the relevant
12 Getting Started Guide, pump User Guide and IFUs
13 for the infusion set and reservoir to ensure
14 that they, with respect to the topics I was
15 addressing, were the same.

16 Q. And just kind of break that down, did
17 you -- are you saying that you looked at the
18 specific infusion set and reservoir IFU in this
19 case and compared them to ones you reviewed in
20 the past?

21 A. I did.

22 Q. Okay. And did you look at and review
23 the User Guide and Getting Started Guide for
24 the insulin pump here to compare it to prior
25 getting started guides and user guides you've

1 WILLIAM J. VIGILANTE, JR.

2 used in the past?

3 A. For the user pump, I did. I did
4 not -- I do not recall having a Getting Started
5 Guide in the Dennert matter.

6 Q. And when you reviewed the Getting
7 Started Guide, did you utilize the version that
8 Plaintiff actually had and produced with
9 highlighting in it?

10 A. I had a copy, but I don't believe I
11 have the original, but I had a copy of it.

12 Q. I asked you earlier about what you
13 did to prepare for your deposition. I wanted
14 to break that down a little bit.

15 Part of the preparation you did
16 for this deposition was speaking with
17 Mr. Haverty; is that correct?

18 A. Yes.

19 Q. When did you speak with Mr. Haverty
20 in preparation for the deposition?

21 A. Yesterday.

22 Q. How long did you speak with
23 Mr. Haverty?

24 A. I'm going to approximate between 15
25 minutes and a half hour.

Page 22

1 WILLIAM J. VIGILANTE, JR.

2 Q. Was that the only time you spoke with
3 Mr. Haverty to prepare for this deposition?

4 A. I believe -- I believe so.

5 Q. Did you speak with anyone else to
6 prepare for the deposition today?

7 A. I did not.

8 Q. And did you spend any time reviewing
9 materials or documents to prepare for the
10 deposition today?

11 A. Yes.

12 Q. How long do you think you spent to do
13 that?

14 A. In total, yesterday I probably spent
15 a little over three hours.

16 Q. Did you spend any time prior to
17 yesterday preparing for the deposition?

18 A. I don't recall.

19 MR. MERRELL: I'm going to mark
20 as Exhibit No. 4 and hand to you an email
21 and letter provided by Mr. Haverty on
22 July 31st, 2018 disclosing you as an
23 expert.

24 I have a copy for you.

25 - - -

Page 23

1 WILLIAM J. VIGILANTE, JR.

2 (Whereupon, Exhibit 4 was
3 marked for identification.)

4 - - -

5 BY MR. MERRELL:

6 Q. Do you understand you were disclosed
7 as an expert on behalf of the Plaintiffs on
8 July 31st, 2018?

9 A. I don't know what date I was
10 disclosed, but it was my understanding that I
11 would be.

12 Q. Do you recall when you were first
13 contacted regarding this case by Plaintiff's
14 case?

15 A. Not offhand.

16 Q. Do you know who initially contacted
17 you about this case for Plaintiffs?

18 A. I think it was Mr. Haverty, I'm
19 pretty sure it was.

20 Q. Do you know if it was this calendar
21 year, was it in 2018?

22 A. Offhand, I don't know.

23 Q. Do you have your billing records
24 available?

25 A. Yes.

Page 24

1 WILLIAM J. VIGILANTE, JR.

2 Q. When is the first notation you have
3 for time you spent on this case?

4 A. It looks like July 23rd, 2018.

5 Q. And how much time did you bill that
6 day?

7 A. Just about an hour.

8 Q. Do you know if that was reviewing the
9 file or speaking with somebody?

10 A. Both.

11 Q. And who did you speak with that day?

12 A. Mr. Haverty.

13 Q. So prior to July 23rd, 2018, you did
14 not perform or conduct any work in this case;
15 is that accurate?

16 A. Nothing that I billed for.

17 Q. Do you believe that you conducted any
18 activities or work prior to July 23rd, 2018
19 that you did not bill for?

20 A. I would have spoken with Mr. Haverty
21 about the case prior to that.

22 Q. Okay. What amount of time, if any,
23 do you believe you would have spent on this
24 case prior to July 23rd, 2018?

25 A. I don't know. I can tell you that

Page 25

1 WILLIAM J. VIGILANTE, JR.

2 the inquiry for the case was in June of 2018.

3 Q. And what do you mean by "inquiry"?

4 A. When Mr. Haverty called to speak
5 specifically to me about the case.

6 Q. So you were first contacted about
7 this case in June of 2018; is that accurate?

8 A. Yes.

9 Q. And you were contacted by
10 Mr. Haverty?

11 A. Specifically, regarding this case,
12 yes.

13 Q. How much time did you spend on this
14 case between July 23rd and July 31st to prepare
15 your expert report?

16 A. One more time?

17 Q. How much time did you spend to
18 prepare your expert report between July 23rd,
19 2018 and July 31st, 2018?

20 A. So it looks like the total time I
21 billed for is 7.75 hours or thereabouts.

22 Q. Okay. So the total time you spent in
23 preparing your expert report in this case was
24 about 7.75 hours; is that correct?

25 A. No.

Page 26

1 WILLIAM J. VIGILANTE, JR.

2 Q. Okay. And can you explain that.

3 A. That's the time I billed.

4 Q. Okay. So the total time that you
5 billed in preparation for your expert report in
6 this case is 7.75 hours; is that correct?

7 A. As of July 31st, 2018, that's
8 correct.

9 Q. What is the -- in your -- in your
10 billing information that you have in front of
11 you, what is the last date that you have there
12 for time you've either billed or time that
13 you've noted as time to bill?

14 A. Bill time, the last entry was
15 7/31/2018.

16 Q. And did you send that bill to
17 Mr. Haverty?

18 A. Yes.

19 Q. After July 31st, 2018, have you kept
20 records of how much time you spent in this
21 case?

22 A. I would have logged time that I spent
23 on this case since then.

24 Q. Do you have those in front of you or
25 available to you?

Page 27

1 WILLIAM J. VIGILANTE, JR.

2 A. I do not.

3 Q. Do you have an estimate of about how
4 much time you spent on this case since that
5 bill on July 31st, 2018?

6 A. I know it's more than a little over
7 three hours, but I don't know where the high
8 end is.

9 Q. Is it less than ten hours; do you
10 think?

11 A. I don't know.

12 Q. Following the issuance of your report
13 on July 31st, 2018, what work did you do in
14 this case?

15 A. There were additional depositions
16 that were provided to me. I think I mentioned
17 them a little earlier in the deposition. Those
18 included exhibits. So other than reviewing
19 those documents and preparing for the
20 deposition, I don't have a specific
21 recollection of what other work I may have
22 done.

23 Q. And your review of information and
24 depositions since the issuance of your report
25 on July 31st, 2018, has that changed or altered

Page 28

1 WILLIAM J. VIGILANTE, JR.
2 anything that you put in your expert report
3 initially?

4 A. It did not.

5 MR. MERRELL: I'm going to mark
6 as Exhibit 5 the copy I have of your
7 expert report.

8 - - -

9 (Whereupon, Exhibit 5 was
10 marked for identification.)

11 - - -

12 BY MR. MERRELL:

13 Q. And I'll ask you a few questions and
14 then I want to turn to your CV and I'll come
15 back to this, but I'm just trying to cover and
16 address all of the materials you reviewed as
17 part of this case.

18 Can you look at page three of
19 your report.

20 A. Sure.

21 Q. There's a list of available materials
22 on page three; do you see that?

23 A. Yes.

24 Q. Is this list a complete list if you
25 add the more recent depositions you received,

Page 29

1 WILLIAM J. VIGILANTE, JR.
2 the Luci Brackin deposition, the Weaver
3 deposition and the Bettis deposition?

4 A. A complete list of what?

5 Q. Of the materials that were available
6 for you to review to provide your opinions.

7 A. Specifically, for this case, I
8 believe so.

9 Q. I notice your -- the list of
10 deposition transcripts, I don't see the
11 deposition transcript of Afshin Bazargan; is
12 that a deposition you reviewed as part of this
13 case?

14 A. I don't believe so.

15 Q. I also don't see Suzanne
16 McConnell-Montalvo; is that one you reviewed as
17 part of your review in this case?

18 A. I don't know if that one was -- I've
19 included it in my file. I had reviewed her
20 deposition dated June 23rd, 2015. I don't know
21 why I didn't include it in my material
22 available.

23 Q. Okay. So although it's not included
24 in the available materials, that is one you
25 have reviewed?

1 WILLIAM J. VIGILANTE, JR.
2 A. I had reviewed, yes.
3 Q. Have you reviewed the deposition of
4 Dr. Gosmanov?
5 A. I don't believe I have.
6 Q. You also list under Available
7 Materials, various medical records; do you see
8 that?
9 A. Yes.
10 Q. Do you have -- do you know if you
11 have a complete set of medical records in this
12 case?
13 A. I do not know that.
14 Q. Which medical records do you believe
15 you've reviewed?
16 A. I don't recall exactly what medical
17 records there were. I did not include them on
18 my laptop because they were rather -- there was
19 a lot of them, but I did include them on the
20 disc.
21 Q. Sorry, keep going.
22 A. So I don't recall spending any great
23 amount of time and energy going through all of
24 her medical records regarding pre and
25 post-incident treatment.

1 WILLIAM J. VIGILANTE, JR.
2 deposition, so I can't say that I got every
3 page.
4 Q. What about the Vardi deposition, did
5 you -- have you reviewed every page of that?
6 A. I don't recall at this point.
7 Q. And the -- this recent Anthony
8 Vicente's deposition, did you review every page
9 of that?
10 A. I can't recall if I had done that
11 either.
12 Q. Do you know if you reviewed all of
13 Mr. Brackin's deposition?
14 A. Yes.
15 Q. Do you know if you read all of
16 Mr. Duarte's deposition?
17 A. John Duarte, I had.
18 Q. Okay. Have you reviewed all of Karen
19 Fisk's deposition?
20 A. I have.
21 Q. And have you reviewed all Mark
22 Curtis's deposition?
23 A. I have.
24 Q. And have you reviewed all of the Rabi
25 Gharabli deposition?

1 WILLIAM J. VIGILANTE, JR.
2 Q. Do you know about how much time you
3 spent looking at medical records?
4 A. I do not.
5 Q. Do you think it was less than three
6 hours?
7 A. I would imagine so.
8 Q. Do you think it was less than an
9 hour?
10 A. I -- probably.
11 Q. Were you given any guidance at all as
12 to particular materials, depositions to focus
13 on in this case?
14 A. Well, I imagine that the ones that
15 were provided with I was supposed to -- well, I
16 don't know what Mr. Haverty's intent was.
17 But the material that I was
18 provided with is the stuff I looked at. Other
19 than the various medical records, I typically
20 don't get involved in pinnacle issues related
21 to pre and post-treatment.
22 Q. With respect to the deposition, did
23 you read every page of the depositions you were
24 provided?
25 A. I skimmed Antatoly's current

1 WILLIAM J. VIGILANTE, JR.
2 A. I have.
3 Q. Have you reviewed all of Randy
4 Adair's deposition?
5 A. Yes.
6 Q. Now, with respect to the medical
7 records, were there certain ones that you were
8 asked to focus on or look at?
9 A. I don't recall being asked to look at
10 or focus on any specific medical records.
11 Q. How did you determine which medical
12 records to look at or review?
13 A. I opened the files to see what they
14 were addressing, and if I didn't find them
15 relevant, I didn't spend a great time --
16 great -- great amount of time looking at them.
17 Q. Were there any particular medical
18 records that were important to your opinions
19 that you reviewed that you can think of?
20 A. I don't recall certainly everything
21 that was in there. I recall either between the
22 depositions and maybe some of the medical
23 records identifying when Mrs. Brackin was
24 recommended to use the subject pump, when she
25 began using the subject pump, but other than

1 WILLIAM J. VIGILANTE, JR.
2 that, I don't recall seeing anything relevant.
3 Q. Have you reviewed the testing that
4 Medtronic conducted on the insulin pump, the
5 reservoir and the infusion set in this case at
6 all?
7 A. What kind of testing?
8 Q. Well, I'll represent to you that
9 Medtronic conducted testing specifically
10 looking at the functionality of the insulin
11 pump at issue here, Ms. Brackin's insulin pump,
12 the reservoir and the infusion set. And I'm
13 asking whether or not that's testing -- the
14 results of the testing is something you
15 reviewed in coming to your opinions?
16 A. Is that post-incident testing?
17 Q. This testing would have been
18 post-incident, yes.
19 A. Nothing is coming to mind at the
20 moment.
21 Q. And perhaps, I don't know if this
22 will jog your memory or not, but the testing
23 was conducted in May of 2017. Is that anything
24 that sounds familiar as something you reviewed?
25 A. I don't recall that material offhand.

1 WILLIAM J. VIGILANTE, JR.
2 doing business as Vigilante Consulting, LLC, so
3 it's registered with the state as a d/b/a.
4 Q. And prior -- well, strike that.
5 Did you begin the Vigilante
6 Consulting, LLC in 2015?
7 A. Yes.
8 Q. And your work for Vigilante
9 Consulting, has that all been litigation work?
10 A. No.
11 Q. Okay. What other work have you done
12 with Vigilante Consulting?
13 A. So I run the forensic investigation
14 side of the business through Vigilante
15 Forensic. I run traditional consulting through
16 Vigilante Consulting, LLC.
17 Q. With respect to the Vigilante
18 Consulting, how much work have you done that's
19 non-litigation consulting?
20 A. It's probably, depending upon what
21 projects I am or not involved in, a small part
22 of overall work.
23 Q. Okay. Would you say that the
24 litigation consulting you do that is serving as
25 an expert report, is that 95 percent plus of

1 WILLIAM J. VIGILANTE, JR.
2 Q. I wanted to turn back to your CV. I
3 forgot what we marked it as an exhibit. I
4 think it may be four.
5 A. Three.
6 Q. And first of all, what is your hourly
7 rate you're charging?
8 A. My current hourly rate is 395 an hour
9 for all case-related work, except for
10 videotaped testimony, which is I charge at 495
11 an hour.
12 Q. And the videotape deposition, do you
13 charge that \$495 an hour as, as a premium or
14 above if it was not videotaped; is that
15 accurate?
16 A. If it was a non-videotaped
17 deposition, it would be 395 an hour.
18 Q. And turning to your CV, what is
19 the -- what is the current company you work at?
20 A. I work technically for Vigilante
21 Consulting, LLC.
22 Q. And I notice that your CV says
23 Vigilante Forensic. Is there a distinction at
24 all?
25 A. Well, legally, Vigilante Forensic is

1 WILLIAM J. VIGILANTE, JR.
2 the work you've done with Vigilante Forensic --
3 well, strike that. Let me ask it a different
4 way.
5 Would you say that your work
6 since you started Vigilante Consulting in 2015,
7 that 95 percent of your -- 95 percent plus of
8 your work has been litigation consulting as an
9 expert?
10 A. Under both Vigilante Consulting and
11 Vigilante Forensic, it's probably about that.
12 Q. Have you done any consulting for any
13 medical device companies since 2015 with
14 Vigilante Consulting?
15 A. I have not.
16 Q. Prior to your work with Vigilante
17 Consulting, were you at Robson Forensic?
18 A. Yes.
19 Q. And were you there from 2003 to 2015?
20 A. Correct.
21 Q. And your title there was associate?
22 A. That's my understanding.
23 Q. Were you ever made a principal there?
24 A. No.
25 Q. The work you did at Robson Forensic,

1 WILLIAM J. VIGILANTE, JR.
2 was it similar to the work that you're doing
3 now at Vigilante Consulting and Vigilante
4 Forensic?
5 A. Yes.
6 Q. While you were at Robson Forensic
7 from 2003 to 2015, was the amount of litigation
8 expert work you did, was that 90 to 95 percent
9 of the work you did?
10 A. I think over time, over the -- I
11 don't know how long I was there, 13 years or
12 so, approximately, that's what it was
13 approximately. That was billable time.
14 Q. And you say "billable time," would
15 there have been non-billable time where you
16 prepared proposals, or what would the
17 non-billable time be?
18 A. Partly that. I also was an area
19 manager for the company for approximately the
20 last five years I was with them, so I had
21 managerial responsibilities over the
22 Philadelphia office, including employment,
23 marketing, et cetera.
24 I was also the area -- or the
25 practice group leader for the human factors

1 WILLIAM J. VIGILANTE, JR.
2 practice group, so I had a lot of
3 responsibilities related to peer reviewing
4 other people's work, hiring and -- and so forth
5 with regard to other human factors, experts
6 promoting the practice, billing the practice,
7 et cetera. So it was a lot of non-billable
8 time related to those two other titles or
9 positions.
10 Q. What is your approximate income then
11 with Vigilante Consulting over the last year?
12 A. I don't know offhand.
13 Q. You don't have any estimate at all?
14 A. I don't have a good estimate, and
15 it's confidential, so I can't provide it even
16 if I did have an estimate.
17 Q. So the figure itself would be
18 confidential?
19 A. Yes.
20 Q. Even without regard to where the
21 income came from?
22 A. Yes.
23 Q. Your work with -- well, strike that.
24 Prior to Robson Forensic, you
25 were at A-R-C-C-A; is that correct?

1 WILLIAM J. VIGILANTE, JR.
2 A. I was an independent contractor for a
3 company called ARCCA, A-R-C-C-A.
4 Q. And what sort of work did you do at
5 ARCCA?
6 A. Forensic investigations.
7 Q. Was that also primarily litigation
8 work?
9 A. I believe so. You know, I don't
10 remember every project I did for -- for ARCCA,
11 but they were all forensic related. Whether or
12 not they were all in litigation, I can't say,
13 but I don't recall.
14 Q. Was 95 percent plus of the work you
15 did at ARCCA, was it litigation work?
16 A. I have no idea.
17 Q. So I guess it was a long time ago.
18 And then prior to that you worked at
19 International Business Machines Corporation
20 from 1998 to 2003?
21 A. No.
22 Q. Well, I'll just ask you a non-leading
23 question.
24 Did you work -- prior to ARCCA,
25 did you work at IBM?

1 WILLIAM J. VIGILANTE, JR.
2 A. So it's a little bit confusing. If
3 you allow me, I can explain it.
4 Q. Yeah, absolutely.
5 A. Okay. So I worked for the IBM
6 Corporation from 1997 until July 2003 when I
7 left IBM to join Robson Forensic, slash, Robson
8 Lapina at the time.
9 In approximately
10 August/September 2001, while I was employed by
11 IBM, I worked for ARCCA as an independent
12 contractor, essentially, moonlighting with the
13 permission of my management staff at IBM, doing
14 forensic consulting. So my time at ARCCA
15 overlapped my time at the IBM Corporation, and
16 my time at ARCCA ended also when I joined
17 Robson Forensic in July 2003.
18 Q. Your litigation work you've done over
19 the years for these various entities, do you
20 have a percentage that was plaintiff versus
21 defendant that you can think of?
22 A. Historically, it's probably about
23 60/40, plaintiff/defendant.
24 Q. The 60 percent of the work
25 historically has been for the plaintiff?

1 WILLIAM J. VIGILANTE, JR.
2 A. Yes.
3 Q. Since you started Vigilante Forensic,
4 has the same held true?
5 A. I can't say it's exactly the same,
6 but it's approximately. I think maybe about 65
7 plaintiff, 35 defendant with Vigilante
8 Consulting or Vigilante Forensic.
9 Q. I take it you've never worked for a
10 medical device company?
11 A. Not that I'm aware of.
12 Q. And you never worked at the FDA?
13 A. I have never worked at the FDA.
14 Q. And you've never done any consulting
15 for the FDA regarding medical devices?
16 A. Not with regard to medical devices,
17 with regard to prescription and
18 non-prescription medication labeling.
19 Q. But no work with the FDA regarding
20 medical devices; is that accurate?
21 A. That's correct.
22 Q. And have you ever done any consulting
23 at all for a medical device company?
24 A. Not that I'm aware of.
25 Q. Have you ever -- strike that.

1 WILLIAM J. VIGILANTE, JR.
2 Information Association. I can't say that the
3 folks that were a part of that organization
4 that we were interacting with were not involved
5 in medical device manufacturing, and part of
6 that work was the research related to warnings
7 and instructions for medical -- excuse me,
8 drug-related products.
9 Q. That would have been back in
10 2000/2001?
11 A. It would have been from, I would say,
12 '97 to 2001.
13 Q. So this work you did from 1997 to
14 2001, you don't know whether or not it involved
15 a medical device company at all?
16 A. I don't recall any specific devices,
17 but I can say it didn't.
18 Q. Uh-hum. The work that you did, do
19 you recall there being prescription drugs or
20 over-the-counter drugs that you looked at?
21 A. I know that my research specifically
22 focused on over-the-counter medication labeling
23 and prescription drug advertising.
24 Other projects that I worked on,
25 one that was in the cognitive ergonomics

1 WILLIAM J. VIGILANTE, JR.
2 So you've never been asked by a
3 medical device company to write labeling, for
4 example, or instructions?
5 A. I have not.
6 Q. And you've never been asked by a
7 medical device company to prepare warnings for
8 a medical device?
9 A. I have not.
10 Q. You've never been asked by a medical
11 device company to evaluate their warnings,
12 labeling or instructions?
13 A. I don't believe so.
14 Q. And you've never been asked by the
15 FDA to evaluate the warnings, labeling or
16 instructions of a medical device?
17 A. I don't believe so.
18 So I have to amend one or two of
19 those answers. With regard to a medical device
20 company and whether I've been asked to either
21 draft or assess their warnings and
22 instructions, I don't know. I can't say that I
23 haven't.
24 In my research during graduate
25 school, we were doing work for the Drug

1 WILLIAM J. VIGILANTE, JR.
2 laboratory at North Carolina State University,
3 I don't recall all of them. There were other
4 medical and drug-related products that were
5 looked at and other studies that I helped with.
6 Q. Okay. So in this time period from
7 1997 to 2001, you don't know whether it
8 involved a medical device company, correct?
9 You don't know whether it
10 involved a medical device company?
11 A. I can't say that it didn't.
12 Q. Since then, have you had any
13 consulting work for a medical device at all?
14 A. Not that I'm aware of.
15 Q. I take it you've never been involved
16 in the design process of a medical device?
17 A. Not that I'm aware of.
18 Q. You've never been involved in a risk
19 analysis for a medical device company?
20 A. On behalf of a medical device
21 company, that's correct, but I have done a risk
22 analysis of a medical device.
23 Q. The risk analysis you've done for a
24 medical device, is that on behalf of a
25 plaintiff in litigation?

1 WILLIAM J. VIGILANTE, JR.
2 A. Yes.
3 Q. And how many times have you done
4 that?
5 A. In the Dennert matter and in this
6 one, were the only two insulin pumps that I can
7 recall, and I don't recall if I've worked on
8 another medical device matter in the -- in my
9 forensic practice prior.
10 Q. Okay. And the Dennert matter was
11 around 2016?
12 A. I don't recall specifically when that
13 was, but it's at least a couple of years.
14 Q. Okay. Prior to the Dennert matter,
15 though, you can't, sitting here today, you
16 can't think of any other medical device
17 litigation where you were asked to analyze the
18 risk or labeling of a medical device?
19 A. The only one that I can think of was
20 an over-the-counter device for pain relief, but
21 I don't recall any other prescription-type
22 medical device products offhand.
23 Q. Okay. And you've never been involved
24 in a 510(k) application or submission for a
25 medical device?

1 WILLIAM J. VIGILANTE, JR.
2 under FDA regulations?
3 A. I'm not sure what you're asking me.
4 So under FDA regulations that it needs to be
5 done during design and development, or are you
6 asking --
7 Q. I'll rephrase.
8 A. I'm sorry, go ahead.
9 Q. Sure. I'll just rephrase it.
10 Well, let me ask you this: Do
11 you consider yourself to be an FDA regulatory
12 expert with regard to submissions of PMA or
13 510(k) or product?
14 A. I do not hold myself out as an expert
15 in regulatory submissions.
16 Q. Okay. Do you hold yourself out as an
17 FDA regulatory expert on the design and
18 development process for medical device?
19 A. I do not hold myself out as a
20 regulatory expert.
21 Q. Do you hold yourself out as a --
22 strike that.
23 Do you hold yourself out as an
24 FDA regulatory expert in any context?
25 A. In any context, I don't know. I

1 WILLIAM J. VIGILANTE, JR.
2 A. Not that I'm aware of.
3 Q. And you've never been involved in a
4 premarket approval submission or process for a
5 medical device?
6 A. I don't believe I have.
7 Q. And you never performed a risk
8 analysis or design validation according to FDA
9 regulations?
10 A. On behalf of a manufacturer, I don't
11 believe so.
12 Q. Well, have you ever applied FDA
13 regulations for any risk analysis or design
14 verification project?
15 A. I'm sorry, you're going to have to
16 repeat that.
17 Q. Okay. Have you ever, in any context,
18 have you ever been asked to apply FDA
19 regulations to evaluate a risk analysis?
20 A. I'm not sure that that question makes
21 sense, so I'm going to have to ask you to
22 rephrase it.
23 Q. Okay. Have you ever been -- have you
24 ever been asked to evaluate a specific medical
25 device and its potential risks and hazards

1 WILLIAM J. VIGILANTE, JR.
2 wasn't planning on providing opinions regarding
3 a regulatory requirement in this case.
4 Q. So you do not have any opinions in
5 this case as to whether or not Medtronic or
6 MiniMed complied with FDA regulations or
7 requirements?
8 A. I wasn't planning on it.
9 Q. Sitting here today, you haven't
10 formed any opinions that -- about whether
11 Medtronic complied with any FDA regulations?
12 A. I haven't given it any thought. So I
13 wasn't asked to address it and I wasn't
14 planning on addressing it.
15 Q. And I take it you're not going to
16 provide any opinions as to whether Medtronic
17 complied with FDA labeling requirements?
18 A. I wasn't asked to look to determine
19 whether or not Medtronic complied with FDA
20 labeling requirements.
21 Q. Are you --
22 A. Regulatory requirements.
23 Q. Sorry, I didn't mean to cut you off.
24 Are you leaving the -- that
25 aspect of this case, the FDA regulations and

<p style="text-align: right;">Page 50</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 requirements, are you leaving that to other 3 experts to address? 4 A. I'm not sure that it was a question 5 in the case. If it is, I wasn't asked to 6 address it, and I don't know who is addressing 7 it. 8 Q. Okay. So that hasn't been part of 9 your analysis, whether or not Medtronic and the 10 medical device at issue in this case complied 11 with any FDA regulations or requirements? 12 A. I have not been asked to address 13 whether Medtronic complied with any FDA 14 regulations. 15 We've been going about an hour. 16 Would you like to -- 17 Q. Absolutely. 18 A. -- take a break for a little bit? 19 Q. That's fine. 20 A. Unless there was a better point that 21 you wanted to break at? 22 MR. MERRELL: No, that's fine. 23 THE VIDEOGRAPHER: The video 24 time is now 11:05. We are going off 25 record. This now ends DVD number one.</p>	<p style="text-align: right;">Page 51</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 - - - 3 (Whereupon, a short recess 4 was taken.) 5 - - - 6 THE VIDEOGRAPHER: This begins 7 DVD number two. We are now back on 8 record. The video time is 11:16. 9 BY MR. MERRELL: 10 Q. Dr. Vigilante, you have a Ph.D. from 11 North Carolina State University; is that 12 correct? 13 A. That's correct. 14 Q. What is your Ph.D. in? 15 A. Ergonomics psychology. 16 Q. And I think you testified before is 17 it, technically, is it a doctor of philosophy 18 at that school? 19 A. Yes. 20 Q. And prior to that, you received from 21 North Carolina State University a Master's in 22 Science in Psychology and Ergonomics; is that 23 correct? 24 A. Yes. 25 Q. And then you also have a Bachelor's</p>
<p style="text-align: right;">Page 52</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 of Science and Psychology Cognitive Track at 3 University of Scranton, correct? 4 A. Correct. 5 Q. And just for clarity, you don't have 6 a medical degree? 7 A. I do not. 8 Q. You don't have an engineering degree? 9 A. I do not. 10 Q. You don't have a, for example, 11 biomedical engineering degree or anything like 12 that? 13 A. I do not have a biomedical 14 engineering degree. 15 Q. You wouldn't consider yourself to be 16 an engineering expert? 17 A. It depends on the topic. 18 Q. Okay. You wouldn't consider yourself 19 to be a design expert in engineering? 20 A. It depends upon the topic. 21 Q. What aspects of engineering would you 22 consider yourself to be an expert in? 23 A. My expertise is in the design of 24 controls and displays. That is the user 25 interaction of products. That's what the field</p>	<p style="text-align: right;">Page 53</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 of ergonomics and human factors is focused on. 3 It's a design-based science. 4 At the IBM Corporation, I was 5 categorized as a human factors engineer. 6 Oftentimes, in my field, at least in the past, 7 was referred to as ergonomics -- or, excuse me, 8 engineering psychology or cognitive 9 engineering. 10 So from a litigation, legal 11 perspective, I'm not a professional engineer, 12 but I do have training in product design, 13 particularly with respect to user interface, 14 and controls, displays, instructions and 15 warnings. 16 Q. Is your expertise in engineering, is 17 it limited to ergonomics and human factors? 18 A. Yes. 19 Q. And obviously, you're not an 20 endocrinologist? 21 A. I am not. 22 Q. And not a neurologist, correct? 23 A. I am not. 24 Q. And I take it you're not here to 25 provide any sort of clinical or medical</p>

<p style="text-align: right;">Page 54</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 opinions in this case; is that correct? 3 A. That is correct. 4 Q. And you're not going to provide any 5 opinions in this case as to medical causation; 6 is that correct? 7 A. I was not going to provide any 8 opinions regarding medical causation. 9 Q. I take it from your report -- well, 10 strike that. 11 Your report focuses primarily on 12 instructions and labeling and human factors 13 issues; is that correct? 14 A. It does address those issues. 15 Q. Are you going to be providing any 16 design opinions in this case? 17 A. Other than the fact that the design 18 allowed for -- created the potential for a 19 common slip or lapse to result in a 20 catastrophic injury, and therefore it should 21 have been fixed through design consistent with 22 the safety hierarchy and basic design 23 guidelines, recommendations and basic human 24 factors guidelines and recommendations. 25 Q. Okay. But you never designed a</p>	<p style="text-align: right;">Page 55</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 medical device, correct? 3 A. I have not. 4 Q. Are you going to be providing an 5 opinion as to an alternative design for the 6 infusion set at issue here? 7 A. I was not providing an opinion 8 regarding alternative design. It's my 9 understanding that there were alternatives, but 10 I'm not providing that -- that opinion. 11 Q. Okay. So I take it you would leave 12 the issues of alternative designs and 13 alternative membrane material, for example, you 14 would leave that to Mr. Klimowicz and other 15 experts in the case? 16 A. I am not addressing the design of 17 alternative membranes. I would assume that 18 other experts are addressing that. 19 Q. Okay. You're -- you're addressing 20 instructions for use and labeling with respect 21 to the design components you discussed; is that 22 accurate? 23 MR. HAVERTY: Objection. 24 THE WITNESS: That is part of my 25 analysis.</p>
<p style="text-align: right;">Page 56</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 BY MR. MERRELL: 3 Q. I think you've been asked some of 4 these questions before, but I just want to 5 confirm nothing has changed since your last 6 deposition. 7 Are you familiar at all with a 8 design history file for a medical device? 9 A. Any medical device or the specific 10 ones involved in this case? 11 Q. Generally speaking, a design history 12 file for a medical device. 13 A. I don't believe so. 14 Q. Are you familiar with a medical 15 device history for a medical device generally? 16 A. Not offhand. 17 Q. And you don't know what regulations 18 govern a design history file for a medical 19 device, correct? 20 A. Not offhand. 21 Q. Okay. And you never maintained or 22 created a design history file for a medical 23 device? 24 A. Not that I'm aware of. 25 Q. Other than the 2000 and 2016</p>	<p style="text-align: right;">Page 57</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 guidances on human factors for a medical device 3 issued by the FDA, are you familiar with any 4 other FDA regulations or guidances with respect 5 to medical devices? 6 A. Offhand, I don't recall any. 7 Specifically, those were the two that I pointed 8 to in my report. 9 Q. So in your report, you don't point to 10 any other FDA guidances or regulations other 11 than the 2000 and 2016 human factors guidances? 12 A. That's correct. 13 Q. And is it correct that the first time 14 you reviewed the 2016 guidance was part of your 15 review in the Dennert case? 16 A. I don't recall what my testimony was, 17 so whatever it was in the Dennert case, I would 18 stand by it. 19 Q. Okay. Maybe that's a good question. 20 Do you stand by the testimony you previously 21 provided on two separate dates for the Dennert 22 case? 23 A. As far as I know. 24 Q. You don't have any changes or 25 retractions at all for those depositions?</p>

<p style="text-align: right;">Page 58</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. I certainly don't recall what 3 questions were asked or answers that were 4 provided, but there's nothing that stands out 5 that I wanted to correct on the record. 6 Q. Okay. 7 A. At this moment. 8 Q. And I take it you don't recall ever 9 reviewing the 2000 and 2016 guidance on human 10 factors issued by the FDA prior to your 11 involvement of the Dennert case? 12 A. At this point, I don't recall. 13 Q. And given your answer, I take it you 14 never reviewed the -- other than these two 15 guidances, you never reviewed any FDA 16 regulations on medical device labeling or 17 instructions for use? 18 A. I don't believe that's correct, but I 19 don't recall anything specific offhand. 20 Q. Okay. And in what context do you 21 think you might have reviewed some other 22 regulation other than these two guidances? 23 A. It may have been done in my research 24 for either the Dennert case or this case or 25 another case. I don't recall offhand the</p>	<p style="text-align: right;">Page 59</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 specific regulation. 3 Q. Okay. Sitting here today, you can't 4 point to another regulation or guidance 5 relating to medical devices on labeling and 6 instructions for use other than those two 7 guidances we've already discussed from 2000 and 8 2016? 9 A. Not offhand. 10 Q. And are you familiar with ISO 14971 11 application of risk management for -- to 12 medical devices? 13 A. I don't recall if I've reviewed that 14 standard or not. 15 Q. It's not something you've applied in 16 this case, though? 17 A. It is not. 18 Q. You have applied ANSI standards in 19 this case; is that correct? 20 A. I did reference a specific ANSI 21 standard in this case. 22 Q. Your references are contained on page 23 25 of your expert report; is that correct? 24 A. That's correct, specific references. 25 Q. And these references as one through</p>
<p style="text-align: right;">Page 60</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 11 are ones that appear as references 3 throughout your report; is that correct? 4 A. That's correct, they're cited in the 5 report. 6 Q. One of the -- the ANSI one I see here 7 is Z535.6, product safety information on 8 product manuals, instructions and other 9 collateral materials; do you see that? 10 A. Yes. 11 Q. Do you know whether or not this would 12 apply to a medical device? 13 A. It was part of the standard of care 14 industry knowledge at the time that the Getting 15 Starting Guide was manufactured and provided 16 with the subject pump. 17 Q. Do you know if the FDA -- I'm sorry, 18 keep going. 19 A. And the training of the subject pump. 20 Q. Do you know if the FDA utilizes the 21 ANSI standard you've identified here in its 22 regulation of the labeling of medical devices? 23 A. Offhand, I do not. 24 Q. And you've never performed a risk -- 25 strike that.</p>	<p style="text-align: right;">Page 61</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 You never performed a formal 3 risk analysis for a medical product? 4 A. On behalf of a medical device 5 manufacturer, I don't believe so. 6 Q. The only risk analysis you would have 7 performed would be on behalf of a plaintiff in 8 a litigation; is that accurate? 9 A. The only ones that I'm aware of would 10 have been done in conjunction with my 11 investigation of a forensic -- excuse me, a 12 forensic investigation of an incident that 13 occurred involving a product, medical product. 14 Q. And would that risk analysis for 15 those circumstances for a medical device, would 16 that have been looking at specific issues or 17 the entire risk analysis for the device? 18 A. Specific issues. 19 Q. So you haven't done a comprehensive 20 risk analysis for a medical device in any 21 context? 22 A. I have not. And it's not necessary 23 for the work that I'm doing. 24 Q. Are you aware or familiar that the 25 insulin pump at issue in this case, the 523,</p>

1 WILLIAM J. VIGILANTE, JR.
2 was approved by the FDA through the PMA
3 process?
4 A. It's my understanding it was.
5 Q. And are you aware that the reservoir
6 and infusion set were cleared through the
7 510(k) process by the FDA?
8 A. I don't recall which specific process
9 they went through.
10 Q. Does the fact that it was PMA
11 approved, the devices were PMA approved or
12 510(k) cleared by the FDA, does that have any
13 impact on your opinions at all?
14 A. It does not.
15 Q. Does the FDA's view of the safety and
16 effectiveness of these devices and their
17 labeling, does that have any impact on your
18 opinions?
19 A. Specifically, on my opinions, they do
20 not.
21 Q. So you come to your opinions
22 regarding the labeling and instructions for use
23 and the safety and efficacy of these products
24 based on your analysis, and the FDA's review is
25 not germane to it; is that accurate?

1 WILLIAM J. VIGILANTE, JR.
2 safety standpoint, a human factors standpoint,
3 and came to my opinions based upon my training,
4 my education and my experience in the standard
5 of care for a product designing introducing a
6 product into the market that's going to be used
7 by the typical or average consumer such as the
8 Brackins.
9 MR. HAVERTY: Just note my
10 objection to the record that the FDA does
11 not make safety and efficacy
12 determinations as to 510(k) products.
13 MR. MERRELL: Okay. I'll note
14 your objection, whether or not we agree on
15 it, that's fine.
16 BY MR. MERRELL:
17 Q. And in this case, you haven't done an
18 analysis of efficacy regarding the insulin pump
19 at all; is that correct?
20 A. Regarding the pump, I don't believe I
21 have any opinions regarding the pump.
22 Q. So you don't actually have any
23 opinions at all regarding the insulin pump; is
24 that correct?
25 A. The pump itself, I do not.

1 WILLIAM J. VIGILANTE, JR.
2 MR. HAVERTY: He's not making
3 any judgments about safety and efficacy.
4 THE WITNESS: I conducted an
5 independent investigation independent from
6 what the FDA may or may not have done.
7 BY MR. MERRELL:
8 Q. Okay. That's a fair point. You are
9 not actually making an analysis of the safety
10 and efficacy of these products; is that
11 correct?
12 MR. HAVERTY: As the FDA
13 understands that.
14 THE WITNESS: Not with respect
15 to the manner in which the FDA would
16 understand it.
17 BY MR. MERRELL:
18 Q. Okay. So if you review or analyze
19 safety or efficacy, it's not in the same manner
20 that the FDA does it; is that correct?
21 A. I did not do an exhaustive
22 investigation of what the FDA requirements were
23 or what their processes or what their thought
24 was.
25 I looked at it from a product

1 WILLIAM J. VIGILANTE, JR.
2 Q. Okay. And I think that's helpful --
3 which means I probably don't have to cover --
4 so you're not -- strike that.
5 You're not here to provide any
6 opinions at all about the 523 insulin pump and
7 whether or not it had a malfunction or whether
8 or not it was defective or anything like that;
9 is that correct?
10 A. I'm not providing opinions as to
11 whether or not the pump malfunctioned or if the
12 pump itself was defective.
13 Q. Okay. And you don't have the
14 qualifications to really address that; is that
15 correct?
16 A. I don't know if I do or do not
17 because I wasn't asked to address it.
18 Q. Okay. And you have not addressed
19 that, correct?
20 A. I have not addressed whether the pump
21 was defective or not.
22 Q. And you haven't addressed whether
23 there was actually a malfunction in this case,
24 correct?
25 A. With respect to the pump, I have not.

1 WILLIAM J. VIGILANTE, JR.
2 Q. And sitting here today, you don't
3 know whether or not the FDA found the
4 particular pump or infusion set or reservoir to
5 be safe and effective?
6 MR. HAVERTY: Objection.
7 THE WITNESS: I do know that the
8 FDA -- I don't recall the exact letter
9 that I saw from the FDA regarding the
10 system and the problems with it.
11 I do know that Medtronic did
12 initiate a recall of the infusion set
13 and/or reservoirs I think in late 2017,
14 but I did not go into investigation of
15 what the FDA did or did not do other than
16 that.
17 BY MR. MERRELL:
18 Q. Okay. And you haven't -- you haven't
19 looked, for example, at any FDA warning letters
20 or anything like that with respect to your
21 analysis in this case?
22 A. I do recall one letter from the FDA
23 regarding the infusion set or reservoir
24 and/or -- well, I'll title it as pump system.
25 That's -- offhand, that's the only one that I

1 WILLIAM J. VIGILANTE, JR.
2 understanding. What is the understanding based
3 on?
4 A. My understanding is based upon my
5 conversations with Mr. Haverty and my
6 understanding of the events.
7 Q. And have you conducted any actual
8 experimentation or testing on the infusion set
9 or the reservoir infusion pump to determine
10 whether there actually was a temporary blocked
11 vent?
12 A. I have not inspected and/or tested
13 the specific infusion set and/or pump involved
14 in the matter.
15 Q. Okay. What is the -- what evidence
16 is there specifically you point to for you to
17 come to say that it's your understanding there
18 was a temporary blocked vent?
19 A. Yeah, it's based upon my -- my
20 conversations with Mr. Haverty, which are
21 consistent with what I saw based upon the notes
22 that were taken by Mr. Brackin after the
23 incident regarding what was done and recorded
24 by the pump regarding the fill the night
25 before, and the other records that were

1 WILLIAM J. VIGILANTE, JR.
2 recall.
3 Q. Okay. Have you relied upon that at
4 all in coming to your opinions in this case?
5 A. I did not.
6 Q. And you're not holding yourself out
7 as an FDA expert with respect to matters in
8 this case; is that correct?
9 A. Yeah, I'm not holding myself out as a
10 regulatory expert in this case, I think that's
11 the best way to put it.
12 Q. Okay. I want to turn to another
13 topic just briefly. I'm going to ask you about
14 your opinions relating to the temporary blocked
15 vent issue. Do you understand what I mean when
16 I refer to it as that?
17 A. I believe so.
18 Q. Okay. In your report, are you making
19 a statement or are you coming to an opinion
20 based on your own review and analysis of
21 whether or not there actually was a temporary
22 blocked vent with respect to Mrs. Brackin's
23 infusion set?
24 A. That's my understanding.
25 Q. Okay. So you say it's your

1 WILLIAM J. VIGILANTE, JR.
2 produced with the pump or from the pump.
3 Q. Is it simply that there was a fill
4 the night before that supports your
5 understanding that there was a temporary
6 blocked vent?
7 A. In conjunction with the fact that she
8 was not -- I believe there was no record of
9 her -- Mrs. Brackin, I should say,
10 administering any independent boluses through
11 the evening and morning.
12 Q. Do you know how much insulin the
13 insulin pump delivered on January 15th, 2016?
14 A. Offhand, I do not. I think that my
15 understanding is that the daily dosing history
16 showed a total daily dose of 26.825 units
17 delivered on January 14th and 132.7 units on
18 January 15th following the reservoir fill and
19 infusion set change.
20 Q. Okay. And the 132.7 units on
21 January 15th, does that come from the screen on
22 the insulin pump, the screen shot?
23 A. It came from my understanding from
24 Brackin Exhibit 22.
25 Q. And do you recall offhand if that's

1 WILLIAM J. VIGILANTE, JR.
2 his notes or --
3 A. I'd have to go back and find the
4 exhibit.
5 Q. Okay. I'll probably try to do the
6 same. I don't have the exhibit numbers
7 memorized.
8 MR. HAVERTY: It is the screen
9 shot.
10 BY MR. MERRELL:
11 Q. It is the screen shot. Okay.
12 Have you looked at the screen
13 shots of the insulin pump?
14 A. If they were part of the exhibits, I
15 have.
16 Q. Okay. And you testified earlier that
17 you did not review the testimony of Afshin
18 Bazargan; is that correct?
19 A. I have not.
20 Q. So you did not see his testimony that
21 the 132.7 units could only come from
22 programming basal and/or bolus?
23 A. I am not aware if his testimony in
24 Brackin Exhibit No. 22 are photographs of the
25 different screens of the -- my understanding

1 WILLIAM J. VIGILANTE, JR.
2 reporting or recording in the insulin pump in
3 this case that there was an overdelivery of
4 insulin from the temporary blocked vent?
5 A. It's my understanding the pump does
6 not record that there was a temporary blocked
7 vent event. Blocked vent event.
8 Q. Okay. And is it also your
9 understanding that the insulin pump would not
10 record any amount of delivery of insulin from a
11 temporary blocked vent?
12 A. I did not get into that analysis
13 during my investigation.
14 Q. So given that you didn't go into that
15 analysis, you don't have any awareness in this
16 case that there's a register or number or
17 something in the data from the pump recording a
18 specific amount of overdelivery of insulin from
19 a temporary blocked vent?
20 A. I don't know and I didn't assess the
21 pump to determine how it was recording the
22 amount of insulin delivery associated with a
23 temporary blocked vent event.
24 Q. And you mentioned the priming of 3.1
25 units earlier?

1 WILLIAM J. VIGILANTE, JR.
2 the subject pump.
3 Q. Okay. Do you know if there is a
4 temporary blocked vent and an overdelivery of
5 insulin related to a temporary blocked vent, do
6 you know if the totals of the insulin delivered
7 would appear on that screen for the total
8 insulin delivered for the day?
9 A. One more time?
10 Q. Yeah, it probably wasn't worded real
11 well.
12 If there's a temporary blocked
13 vent that leads to an overdelivery of insulin,
14 do you know whether or not that information is
15 recorded anyplace on the insulin pump?
16 A. If there is a temporary block whether
17 it's recorded on the insulin pump; is that what
18 you're asking me?
19 Q. Yes.
20 A. I'm not aware of a recording that
21 there was a temporary vent block on the insulin
22 pump.
23 Q. Okay. So let's start with this, so
24 you're not -- you don't have any evidence or
25 you're not aware that there's any sort of

1 WILLIAM J. VIGILANTE, JR.
2 A. I don't recall mentioning that, but
3 it is in my report.
4 Q. Okay. Does that impact your analysis
5 at all in determining whether there was a
6 temporary blocked vent?
7 A. I don't believe that it does. It's
8 just part of my understanding of what was
9 occurring.
10 Q. Okay.
11 A. Or what did occur.
12 Q. So the amount of that manual prime of
13 3.1 units, that doesn't impact your opinion
14 whether or not there was a temporary blocked
15 vent in this case?
16 A. As to whether it was 3.1 or 3.2 or
17 3.0, does not.
18 Q. Okay. And if it was -- the prime was
19 10, that wouldn't impact your opinion as to
20 whether or not there was a temporary blocked
21 vent?
22 A. At this point, I don't know.
23 Q. So the amount of the manual prime has
24 no impact on your analysis of whether or not
25 there's a temporary blocked vent?

WILLIAM J. VIGILANTE, JR.

A. Yeah, I don't believe I factored in the specific amount of the manual prime in determining my understanding as to whether or not there was a temporary blocked vent at issue or an event that occurred that caused the overdelivery of insulin to Mrs. Brackin on the 14th and 15th of January.

Q. Did you speak at all with Mr. Brackin in coming to your opinions?

A. I did not.

Q. Have you spoken to any treating physicians at all in coming to your opinions?

A. I have not.

Q. Have you spoken to any other family members of the Brackins in coming to your opinions in this case?

A. I did not. I relied upon Mr. Brackin's deposition testimony for the drafting of my report, and I relied upon Luci Brackin's deposition testimony after my report was written.

Q. Do you agree that Mr. Brackin based on his deposition testimony demonstrated an ability to refill the reservoir consistent with

WILLIAM J. VIGILANTE, JR.

the instructions provided with the getting starting guide, including placing the reservoir over the vial before moving it?

A. I do remember seeing the video of the deposition, I believe, and watching him fill the vial and then remove the vial -- the reservoir from the transfer guard with the correct orientation of the insulin pump vial and reservoir with respect to Medtronic's IFU and Getting Started Guide.

Q. Is there any testimony in this case supporting that Mr. Brackin on the evening of January 14, 2016 incorrectly refilled the reservoir with the orientation of the insulin vial on the bottom?

A. Yeah, I don't recall Mr. Brackin having a specific memory of how he did the actual task on the night of the refill or January 14th.

There's testimony for Mrs. Luci Brackin that the need to have the reservoir over the vial, insulin vial, when removing the reservoir from the transfer guard was not emphasized during the pump training that they

WILLIAM J. VIGILANTE, JR.

all received when Mrs. Brackin began her insulin pump treatment, and I believe that Mr. Brackin had similar testimony.

Q. Okay. But you haven't seen any testimony from any witness that in fact Mr. Brackin had the orientation reversed where the reservoir was on the bottom and the insulin vial was on top?

A. Yeah, it's my understanding that it was just Mr. Brackin and Pamela Brackin present at the time that the infusion set was changed. And, again, I'm not aware of Mrs. Brackin ever having the opportunity to testify or to provide a statement, and I don't recall anything in Mr. Brackin's testimony regarding his being able to remember what the orientation was at the time or the night prior to the 15th of January.

Q. Okay. So then you haven't -- there's an absence of evidence as to what the orientation was the evening of January 14th, 2016; is that correct?

A. There's an absence of witness testimony as to what actually occurred.

WILLIAM J. VIGILANTE, JR.

Q. Okay. There's an absence of witness testimony as to what actually occurred on January 14th, 2016 with regard to the orientation of the reservoir and the insulin vial; is that correct?

A. That's my understanding.

Q. And did you review the deposition testimony of Kristin Bettis where she discussed that she would train patients to place the insulin vial on the bottom on a table with the reservoir on top?

A. I don't believe she testified to that specifically.

Q. Okay. Do you recall seeing any testimony from Kristin Bettis about utilizing a table when going through the refilling process of the reservoir and with the insulin vial?

A. My recall is that she would start with the insulin vial on the table, but I do not recall her showing training or demonstrating having either the vial or the reservoir on the table when removing the reservoir from the transfer guard.

Q. Okay. Is your understanding that

1 WILLIAM J. VIGILANTE, JR.
2 there was a temporary blocked vent in this
3 case, is that an assumption you've made?
4 A. It's my understanding, so it is an
5 assumption.
6 Q. Is it an assumption that you've
7 tested at all?
8 A. It's not an opinion, so there was no
9 need for me to test it, it's just my
10 understanding.
11 Q. So in your analysis of this case, you
12 started with the assumption that there was in
13 fact a temporary blocked vent on
14 January 14th -- 15th 2016?
15 A. No, I did not.
16 Q. Okay. Explain that.
17 A. It's my -- based upon my review of
18 the documents both in the Brackin incident and
19 the Dennert incident that there was a temporary
20 blocked vent -- potential associated with the
21 infusion set and reservoir due to the design of
22 the vents in the manner in which the units were
23 connected and the reservoir was filled with --
24 with insulin, the hazard associated with that
25 was a laid out fairly clearly in the Medtronic

1 WILLIAM J. VIGILANTE, JR.
2 documents for the potential of over or
3 underdelivery of insulin, which, of course, can
4 create or contribute to catastrophic injuries
5 to the patient. Those exists whether or not
6 Mr. or Mrs. Brackin were ever provided with the
7 subject pump and infusion -- infusion set.
8 The second part of my analysis
9 regarding the failure to conduct a proper risk
10 and human factors analysis, again, does not
11 involve whether or not Mr. or Mrs. Brackin were
12 ever given the pump. Those failures preexisted
13 Mrs. Brackin's prescription of the pump. They
14 were actions that Medtronic failed to take that
15 they should have taken much before Mrs. Brackin
16 was ever given the pump or the infusion set or
17 the reservoir to use.
18 Medtronic's failure to provide
19 adequate warnings and instructions also are
20 independent as -- of what Mr. and Mrs. Brackin
21 may or may not have done. Again, those
22 failures preexisted the prescription of the
23 pump and infusion set to Mr. and Mrs. -- or
24 Mrs. Brackin. So that's -- that's what I
25 meant.

1 WILLIAM J. VIGILANTE, JR.
2 Q. Okay.
3 A. What I mean.
4 Q. So you -- go ahead.
5 MR. HAVERTY: Just so we're
6 really clear, his opinions go to the issue
7 of whether or not the product was
8 defective in its design. And that's
9 really essentially what he's talking
10 about, so that's why he says this is
11 independent of what -- what actually
12 happened that night.
13 He's really just here about
14 defective design and inadequate warning
15 with -- in the face of a hazard that could
16 have been foreseeably that's -- so I just
17 want you to understand what the -- the
18 parameters of his opinions are.
19 BY MR. MERRELL:
20 Q. I think, yeah, I'm understanding.
21 So you -- you -- your analysis
22 in this case of the potential hazard that you
23 just discussed and of the instructions for use
24 in human factors issues surrounding it, you --
25 that's really irrespective of what actually

1 WILLIAM J. VIGILANTE, JR.
2 occurred in this case in terms of whether there
3 was a temporary blocked vent; is that correct?
4 A. Whether or not there was a temporary
5 blocked vent that occurred to Mrs. Brackin on
6 the evening of January 14th going into the 15th
7 is not relevant to whether or not Medtronic
8 failed to conduct a proper risk and human
9 factors analysis, whether or not they failed to
10 provide adequate warnings and instructions, and
11 whether or not the product was defective
12 because of their failures.
13 The only thing that's relevant
14 to with respect to my opinions is the
15 causation, and for that causation opinion, I
16 have to make the assumption based upon my
17 understanding that there was indeed or in fact
18 a blocked vent, temporary blocked vent, a
19 blocked vent event that occurred on
20 January 14th going into the 15th of January.
21 Q. So the only way you can make the
22 causation opinion you just referenced which is
23 in your report is through an assumption that
24 there actually was a temporary blocked vent,
25 correct?

WILLIAM J. VIGILANTE, JR.

A. Correct. So if there's not a temporary blocked vent, I would not have been able to connect Medtronic's failure to the defect evident product to the actual injury to Mrs. Brackin. So the injury to Mrs. Brackin, my understanding would be there would have to be a temporary blocked vent event to have occurred to link the failures and the defect to the injury.

Q. Okay. And you haven't evaluated other potential sources or causes of an overdelivery of insulin in this case; is that correct?

A. I have not -- well, I take that back. So, again, it was not part of my analysis to determine whether or not there was a temporary blocked vent event that occurred.

But as I mentioned earlier, based upon my review of the material, I didn't see another potential cause of the overdelivery of insulin, and what I did see was consistent with my understanding and knowledge of these types of events. So I wasn't asked to do the analysis, but in my analysis, I did not find

WILLIAM J. VIGILANTE, JR.

that there was another potential.

Q. Okay. That's helpful. So it was not part of your analysis to determine whether or not there was a temporary blocked vent that actually occurred here?

A. It was my understanding it was an assumption I used to link the causation.

Q. Understood. But it wasn't your analysis to determine whether or not there was a temporary blocked vent that actually occurred?

A. That's correct, I did not set out or was asked to determine that.

Q. Okay. Your -- sort of your bucket is really more into evaluating the hazards we discussed and the human factors issues and instructions for use and labeling issues surrounding it?

A. And design.

Q. And with respect to design, though, I think we already covered this, you're not addressing alternative designs or how the -- the product could have been designed differently; is that correct?

WILLIAM J. VIGILANTE, JR.

A. Again, I have an understanding and assumption that there were other types of alternative designs that were available to eliminate the potential for a blocked vent -- or, excuse me, an over/underdelivery of insulin due to a blocked vent. But I did not do the analysis to show that what those alternative designs were or the feasibility --

Q. Okay.

A. -- of those alternative designs.

Q. So you haven't done any analysis of potential alternative designs or the feasibility of those alternative designs to address this hazard that you've identified; is that correct?

A. I was not asked to do that, and I did not do that, but it's my understanding that there were.

BY MR. MERRELL:

Q. Okay. I'm going object as nonresponsive.

And I take it you -- since you didn't really consider or analyze whether there was a temporary blocked vent or analyze

WILLIAM J. VIGILANTE, JR.

potential causes for overdelivery of insulin, you didn't consider whether or not Mrs. Brackin changed the temporary basal rate, for example, as an alternative?

A. I did not specifically investigate that. I did not see any evidence of it in my review of the file material.

Q. Okay. But you are -- as you're going through this, your analysis per your report, temporary basal rate was not something that was part of your analysis; is that correct?

A. I did not specifically do an investigation to determine that.

Q. And you're not here as a design engineer; you would agree with that?

A. I would be here as a human factors design expert.

Q. You're not offering an opinion that the design of the P-Cap was inappropriate, are you?

MR. HAVERTY: Objection.

THE WITNESS: Yes, I am. Given the risk associated with contaminating the underside of the membrane, it was

1 WILLIAM J. VIGILANTE, JR.
2 something that they should have --
3 Medtronic should have identified during
4 the design and development of the product
5 and then taken steps to eliminate and/or
6 guard against that potential.

7 It's my understanding that there
8 were feasible alternatives at the time it
9 was designed and first manufactured that
10 eliminated and/or prevented this type of
11 hazard from occurring.

12 It's my understanding that the
13 standard and the insulin pump industry
14 pre-2000 was -- was called a Luer Lock
15 that did not have vents that did not have
16 the potential to be blocked and lead to a
17 closed -- temporary closed vent or closed
18 blockage -- excuse me, temporary blockage
19 of the vents because there wasn't any
20 vents.

21 So Medtronic's design to include
22 a waterproof feature of the product, which
23 they never marketed as, introduced a
24 hazard that didn't need to exist, so I
25 would have opinions regarding that topic.

1 WILLIAM J. VIGILANTE, JR.
2 believe that he was asked that in his
3 deposition.

4 Q. Okay. In any case, two years after
5 the incident occurred, you agree he was still
6 able to demonstrate the proper sequence of
7 refilling reservoir including having the
8 reservoir on top of the insulin vial before
9 moving it?

10 A. So I think I need to amend my answer.
11 I don't know that I ever saw the video. I
12 think it was just my understanding based upon
13 the transcript that he was able to demonstrate
14 the procedure consistent with the preferred
15 method of Medtronic during his deposition.

16 Q. Okay. So you haven't actually
17 watched the video of Mr. Brackin's deposition?

18 A. I don't have it listed in my material
19 available, and I don't have a specific
20 recollection, so at this point I don't know.

21 Q. Okay. But based on your review of
22 the reading the deposition transcript of
23 Mr. Brackin, you agree two years after the
24 incident he still demonstrated the ability to
25 correctly refill the reservoir including having

1 WILLIAM J. VIGILANTE, JR.
2 BY MR. MERRELL:

3 Q. I just want to follow up on a couple
4 of things. I asked you earlier about
5 Mr. Brackin and his testimony. And you said
6 you actually saw the video; is that correct?

7 A. I believe so, yes.

8 Q. And you agree then -- and that video,
9 was that about two years after the incident?

10 A. His deposition was March 2018. So
11 we're looking at, I believe, two-plus years if
12 I'm not mistaken.

13 Q. Okay. And Mr. Brackin two-plus years
14 after the incident at issue, he hadn't done any
15 infusion set or reservoir refills since then,
16 had he?

17 A. I don't recall him being asked that,
18 so I don't know.

19 Q. You would agree that there wouldn't
20 really be any reason for him to ever do a
21 reservoir and infusion set change after this
22 date given that his wife passed away; is that
23 correct?

24 A. I don't -- I didn't look into whether
25 or not he had any reason to, and I don't

1 WILLIAM J. VIGILANTE, JR.
2 the reservoir on top of the insulin vial as the
3 last step before removing it?

4 A. Yes, it's my understanding during his
5 deposition that he was -- he was able to
6 demonstrate the preferred method of Medtronic
7 with regard to removal of the reservoir from
8 the transfer guard with the reservoir on top of
9 the insulin vial.

10 Q. And there's -- you agree there's no
11 testimony that Mr. Brackin did not have an
12 appropriate understanding of the steps for
13 refilling the reservoir?

14 A. I don't recall in his testimony that
15 he was specifically asked that question. Yeah,
16 I don't recall him being specifically asked
17 that question.

18 Q. Okay. Maybe I didn't ask the
19 question right. I wasn't really asking
20 specifically about his testimony.

21 You haven't seen any testimony
22 in this case that would indicate that
23 Mr. Brackin did not have an understanding of
24 the appropriate steps of refilling?

25 A. I don't know that he was ever asked

1 WILLIAM J. VIGILANTE, JR.
2 if he had an understanding of the appropriate
3 steps.
4 It's my understanding that after
5 they were given the pump and brought it home,
6 he followed the Getting Started Guide for the
7 five or six times he did the insulin pump -- or
8 infusion set change. I don't recall him being
9 asked if during those five or six times he was
10 following the Getting Started Guide, that he
11 understood or appreciated the need and the
12 preference of Medtronic to have the reservoir
13 over the insulin vial when it was removed from
14 the transfer guard or that the insulin vial --
15 or, excuse me, the reservoir needed to be
16 removed from the transfer guard before the
17 insulin vial. I don't recall him ever being
18 asked those questions.
19 Q. Okay. Well, my question is a little
20 bit different.
21 Have you seen any testimony at
22 all to suggest that Mr. Brackin was not
23 following the appropriate steps from the
24 Getting Started Guide?
25 A. At what point in time?

1 WILLIAM J. VIGILANTE, JR.
2 basis for them. The assumptions I made to
3 do my investigations, if those things
4 change, you know, that's -- that's beyond
5 me at this point.
6 BY MR. MERRELL:
7 Q. Well, I'm just trying to understand
8 your answer, because when I asked you if you
9 are familiar with any testimony to support that
10 Mr. Brackin did not have an appropriate
11 understanding of the refilling, you pointed
12 back to the assumption that there actually was
13 a temporary blocked vent in this case, correct?
14 A. I don't believe that's the exact
15 question you asked me to be fair. But part of
16 my analysis is the assumption that there was a
17 temporary blocked vent that occurred.
18 It very well may be that there
19 was another liquid that contaminated the top of
20 that reservoir other than the insulin, but the
21 most likely cause is the fact that the evening
22 of January 14th Mr. Brackin removed the
23 reservoir while under the insulin vial
24 consistent with the known use of the product
25 that preceded that evening and preceded

1 WILLIAM J. VIGILANTE, JR.
2 Q. At any time.
3 A. Yes.
4 Q. Okay. Which testimony is that?
5 A. Testimony that he changed the
6 infusion set on the evening before January 15th
7 which led to the closed -- temporary closed
8 vent event, which is consistent with changing
9 or removing the vial -- or, excuse me, the
10 reservoir with the vial above it. So that
11 would be evidence of him not doing it correctly
12 all the time at the very least.
13 Q. That's based on your assumption that
14 that actually occurred, correct?
15 A. That's correct.
16 Q. Okay.
17 A. Well, it's my assumption that's what
18 the event was.
19 Q. Okay. Is an assumption, is that
20 evidence?
21 MR. HAVERTY: Objection. You're
22 asking him a legal question.
23 THE WITNESS: Yeah, I mean, you
24 guys are going to have to figure that out
25 at trial. I have my opinions. I have the

1 WILLIAM J. VIGILANTE, JR.
2 Mrs. Brackin's being prescribed the pump in the
3 first place.
4 So this is a known use.
5 Medtronic was well aware of it, and they should
6 have been aware of it when they designed it
7 back in 1999 and 2000. So the testimony
8 evidence that I would point to is the fact that
9 Mr. Brackin changed the vent -- or changed
10 the -- changed the infusion set the evening
11 before Mrs. Brackin was found unresponsive.
12 Q. So the only testimony you're citing
13 as support that Mr. Brackin refilled the
14 reservoir with the reservoir on the bottom and
15 the vial, insulin vial, on top is his testimony
16 that he changed the infusion set on the evening
17 of January 14th, 2016?
18 A. Yes and no.
19 Q. And what is the no?
20 A. Well, there's other testimony. So,
21 for example, Mark Curtis in his -- in his
22 deposition back in 2005 testified as to how he
23 determined what was going on. The fact of the
24 matter was that Mr. Curtis did the same thing
25 that I'm concluding that Mr. Brackin did during

1 WILLIAM J. VIGILANTE, JR.
2 his investigation as to why this was occurring.
3 He removed the reservoir from the transfer
4 guard with the insulin vial over it, even
5 though, he, as I noted in my report, was well
6 aware of and had been trained and had done it
7 multiple times before that he was supposed to
8 remove the reservoir according to the
9 instructions while above the insulin vial.

10 So I think there's other
11 testimony, too, that eventually Medtronic
12 employees became aware of why and how these
13 closed vents -- these blocked vent -- blocked
14 vent events were occurring. So that background
15 information as to Medtronic's knowledge, which
16 is also consistent with the discovery material
17 they provided, it's consistent with the -- the
18 emails from their global help or support center
19 that they were aware of it, consistent with the
20 YouTube videos that I pointed to.

21 So all of that evidence is
22 consistent -- or it shows that the -- the cause
23 of these closed vent is getting material, a
24 liquid or foreign substance, on top of the
25 reservoir before it's connected to the P-Cap,

1 WILLIAM J. VIGILANTE, JR.
2 and that the likely -- most likely cause of
3 that is the end version of the vial in the
4 reservoir while the reservoir is removed. So
5 taking that information and knowledge and
6 applying it to what happened in my
7 understanding of the event that occurred on the
8 14th and 15th of January, Mr. Brackin's
9 testimony would suggest that that's in fact
10 what occurred more likely than not.

11 Q. And Mr. Curtis, who you referenced,
12 he's a former employee of Medtronic; is that
13 correct?

14 A. He was an employee of Medtronic's. I
15 don't know that I know his current state, but
16 he was an employee of Medtronic's.

17 Q. And Mr. Curtis, he doesn't have any
18 awareness at all -- or what occurred with
19 respect to Mr. Brackin?

20 MR. HAVERTY: Objection.

21 THE WITNESS: I have no idea.

22 His deposition testimony was 2015. What
23 he learned after his deposition testimony,
24 I'm not -- I'm not privy to.
25

1 WILLIAM J. VIGILANTE, JR.
2 BY MR. MERRELL:

3 Q. Well, if you don't know whether or
4 not Mr. Curtis was aware at all of what
5 happened on January 14, 2016 with respect to
6 Mr. Brackin specifically, wouldn't you agree
7 you wouldn't be able to cite Mr. Curtis's
8 testimony as to actually what happened that
9 night?

10 MR. HAVERTY: Objection. He
11 already testified to that.

12 THE WITNESS: No, that's not
13 correct.

14 BY MR. MERRELL:

15 Q. So even though Mr. Curtis may or may
16 not have any idea what happened with respect to
17 Mr. Brackin refilling on January 14, 2016, you
18 can somehow rely on his testimony as to what
19 actually did occur?

20 A. Again, I would use Mr. Curtis's
21 testimony again to build the background and
22 understanding as to why contaminants were
23 getting on top of the -- on top of the
24 reservoir and contaminating the P-Cap when it
25 was connected to it. And that was because the

1 WILLIAM J. VIGILANTE, JR.
2 reservoir was being removed from the transfer
3 guard with the insulin vial over it. So I
4 would rely upon that part of Mr. Curtis's
5 testimony to determine and conclude of what
6 happened to Mr. Brackin on the evening of the
7 January 14th.

8 Q. Okay. So because Mr. Curtis
9 demonstrates that it is possible to have liquid
10 on the P-Cap resulting in a temporary blocked
11 vent, you're relying on that to show or
12 demonstrate that in fact it did occur with
13 respect to Mr. Brackin on January 14th when he
14 changed the infusion set?

15 MR. HAVERTY: Objection.
16 Mischaracterizes his testimony.

17 THE WITNESS: Yeah, so I believe
18 Mr. Curtis came to the conclusion that
19 this is why the closed vent -- vents were
20 occurring, not that it was impossible, but
21 this is why they were occurring.

22 And, again, he determined how it
23 occurred based upon his -- his testing
24 once -- once Medtronic had received those
25 two videos from Germany back in 2013. So

1 WILLIAM J. VIGILANTE, JR.
2 he concluded what the cause was. The
3 cause was the user removing the reservoir
4 under the insulin vial, removing it from
5 the transfer guard, and then having the
6 insulin drip or spill or contaminate the
7 top of the reservoir and then connecting
8 the P-Cap to it.
9 So that's what he concluded was
10 occurring. Again, his testimony is part
11 of my understanding and background as to
12 what was going on, what Medtronic's
13 understanding of what was going on. And
14 then looking at Mr. Brackin on the evening
15 of January 14th is consistent of the
16 outcome, the closed vent causing the
17 overdilution of insulin, is consistent
18 with what Mr. Curtis found and what
19 Medtronic was finding, and what was shown
20 in the YouTube videos that I pointed to,
21 what was found in the YouTube videos that
22 Medtronic's global support management team
23 had found back in 2013. So that's how I
24 would use and rely upon Mr. Curtis's
25 testimony.

1 WILLIAM J. VIGILANTE, JR.
2 A. Can we take a break?
3 THE VIDEOGRAPHER: We're now
4 going off the record. The video time is
5 12:13 and this ends DVD number two.
6 - - -
7 (Whereupon, a short recess
8 was taken.)
9 - - -
10 THE VIDEOGRAPHER: We are now
11 back on record. The video time is
12 12:59 and this begins DVD number three.
13 BY MR. MERRELL:
14 Q. Okay. I'm just going to just clean
15 up a few things and backtrack a bit things in
16 my notes.
17 We talked a little bit earlier
18 about the 2016 and 2000 FDA guidance on human
19 factors. That's something that you referenced
20 in your report, correct?
21 A. I reference the 2000 version in my
22 report.
23 Q. Okay. You referenced the 2000
24 version and you have, I think, the 2016 version
25 on the CD over there?

1 WILLIAM J. VIGILANTE, JR.
2 BY MR. MERRELL:
3 Q. Okay. I'm going to object as
4 nonresponsive.
5 You would agree that there's not
6 been any testimony from a witness in this case
7 that there was actually liquid on the reservoir
8 P-Cap on the night of January 14, 2016?
9 A. Again, it's my understanding that
10 Mr. Brackin and Pamela Brackin were the only
11 two present when the infusion set was changed.
12 Mr. Brackin did not testify that he was aware
13 that there was liquid on the reservoir -- or
14 top of the reservoir prior to it being
15 connected to the P-Cap connector.
16 Q. Okay. And you would agree that
17 Mr. Brackin, he -- he never testified that
18 every had at any time refilling the reservoir
19 the insulin vial on the top with the reservoir
20 on the bottom; would you agree with that?
21 A. I don't recall him ever testifying to
22 that.
23 Q. Okay.
24 A. We've been going about another.
25 Q. Yes, sure.

1 WILLIAM J. VIGILANTE, JR.
2 A. Yes.
3 Q. Is it still your understanding that
4 these FDA guidances from 2000 and 2016 are not
5 actually requirements?
6 A. I'm not aware of them being
7 regulations.
8 Q. Okay. So given that they're not
9 regulations, they're not FDA requirements; is
10 that accurate?
11 MR. HAVERTY: Objection. He
12 said what he thought they were, they're
13 not regulations.
14 THE WITNESS: Yeah, they're not
15 regulations.
16 BY MR. MERRELL:
17 Q. Do you know whether or not they're
18 requirements?
19 A. Well, I think that if the FDA had a
20 requirement, it would be a regulation.
21 Q. Okay. So you would think a
22 requirement from the FDA would have to be in
23 the form of a regulation; is that accurate?
24 A. I believe so.
25 Q. And these two guidances are not

<p style="text-align: right;">Page 102</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 regulations, correct? 3 A. The 2000 was not part of a FDA 4 regulation at the time. 5 Q. Is it part of an FDA regulation now? 6 A. I don't know. 7 Q. Do you know if you had all of the 8 human factors evaluations performed by 9 Medtronic for the P-Cap in your assessment? 10 A. I'm aware of the usability studies 11 that were testified to by Susan McConnell. 12 Q. Anything else? 13 A. That's all. 14 Q. So you haven't reviewed anything 15 other than those usability studies testified to 16 by McConnell? 17 A. I don't believe so. 18 Q. Would you agree that if Pamela 19 Brackin did not have a temporary blocked vent, 20 then your opinions would not be causally 21 related to this case? 22 A. With respect to causation, that's 23 correct. 24 Q. You also prepared an expert report 25 and a supplemental expert report in the Dennert</p>	<p style="text-align: right;">Page 103</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 case; is that correct? 3 A. I know I prepared a report. I don't 4 know if I prepared a supplemental report or 5 not. 6 Q. Okay. 7 A. Oh, yeah, I do recall. I did -- I 8 did produce at least one supplemental report. 9 There may have actually been two. 10 Q. Do you recall with your initial 11 report in the Dennert case that you did not 12 have the deposition of Susan McConnell? 13 A. That was the case. 14 Q. And in that initial expert report for 15 the Dennert case, did you indicate that there 16 had not been any human factors analysis by 17 Medtronic? 18 A. Based upon the testimony that I had 19 from Randy Adair and others, did I conclude 20 that. 21 Q. And then after you reviewed the 22 McConnell deposition, did you supplement it to 23 correct that mistake in your original report? 24 A. After I received the McConnell 25 deposition, I updated my report.</p>
<p style="text-align: right;">Page 104</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Q. Other than that one -- 3 A. I'm sorry, I supplemented my report. 4 Q. Other than the one issue with respect 5 to the McConnell deposition, do you stand by 6 the opinions and information you put in your 7 Dennert reports? 8 MR. HAVERY: Objection. Asked 9 and answered. 10 THE WITNESS: I don't remember 11 everything that was in them, but I don't 12 recall anything specifically offhand I 13 don't agree with. 14 BY MR. MERRELL: 15 Q. Do you know if you copied any of the 16 portions of the expert report from Dennert into 17 the Brackin report? 18 A. I did reuse some of the material. 19 Q. Do you know if the Brackins ever 20 reviewed the IFU for the reservoir or infusion 21 set? 22 A. It's my understanding Mr. Brackin 23 testified that they did not, they only relied 24 upon the Getting Started Guide. 25 Q. And did they, similarly, did they not</p>	<p style="text-align: right;">Page 105</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 review the User Guide for the insulin pump? 3 A. I'm -- the testimony is they only 4 used the Getting Started Guide, they only used 5 it during training, and that was the only thing 6 they referenced -- that he referenced after -- 7 after training. 8 Q. Is there any testimony that the 9 Brackins did not understand the Getting Started 10 Guide for the insulin pump? 11 A. I don't think that there was any 12 testimony that -- from Mr. Brackin that he 13 didn't understand the information in the 14 Getting Started Guide. 15 Q. Have you ever been involved in a CAPA 16 process? 17 A. I'm sorry, one more time? 18 Q. Have you been involved in a CAPA 19 process? 20 A. I have not. 21 Q. Have you ever been involved in 22 post-market surveillance program for a medical 23 device? 24 A. I have not. 25 Q. Have you reviewed the transcript from</p>

1 WILLIAM J. VIGILANTE, JR.
2 the 24-hour helpline call that Mr. Brackin
3 placed to Medtronic at all?

4 A. I don't believe so.

5 Q. So you're not aware of any of the
6 information that Mr. Brackin may have conveyed
7 to the Medtronic 24-hour helpline in his call?

8 A. The only information I would have is
9 what Mr. Brackin testified to regarding him
10 calling Medtronic when he received the -- I
11 think there was a failure -- error message that
12 came up on the pump the day -- either the day
13 of or the day after the event.

14 Q. So the only information -- sorry.

15 A. I can't -- motor error I think was
16 the message that appeared on the pump screen.

17 Q. So the --

18 A. He called -- he called Medtronic's
19 helpline to speak -- to speak to -- and spoke
20 with a representative about the motor error
21 message.

22 Q. So the only information you have
23 regarding that phone call that Mr. Brackin
24 placed is from his testimony and exhibits from
25 his deposition?

1 WILLIAM J. VIGILANTE, JR.

2 A. I believe so.

3 Q. Have you been involved at all in any
4 trending analysis of complaints for a medical
5 device manufacturer?

6 A. I have not.

7 Q. And have you ever been involved in
8 assessment or analysis of whether or not there
9 was a signal from trend analysis for a medical
10 device?

11 A. For on behalf of a --

12 Q. No.

13 A. -- medical device?

14 Q. Not limited to that.

15 A. I don't believe so.

16 Q. Did you conduct any sort of
17 assessment or analysis in this case of the
18 complaints coming into Medtronic to assess
19 whether there was any sort of signal to
20 Medtronic regarding a temporary blocked vent,
21 for example?

22 A. I did look at the testimony and the
23 exhibits and the data that came in. Over the
24 years, Medtronic has tracked this in different
25 ways using different error codes. And based

1 WILLIAM J. VIGILANTE, JR.
2 upon the error code that were used, they were
3 coming to different figures, if you will. So I
4 believe that at one point they were looking at
5 identifying a handful of potential temporary
6 blocked vent events.

7 They then -- when they looked --
8 relooked at the error codes, they moved that
9 up -- that estimate up until about 90 events a
10 year, and then when they moved to the -- I
11 think it's EO or EA30 or 35 code in between
12 2013 and 2014, after the health care -- Dear
13 Health Care letter, I think they determined
14 that there were on the order of 750 reported
15 events.

16 So I think that's my
17 understanding of the -- at least the history of
18 the recording and reporting of these types of
19 events.

20 Q. Did you try to make any sort of
21 analysis as to the -- the occurrence level,
22 whether it's extremely rare, rare or common in
23 terms of a temporary blocked vent?

24 A. I didn't do an in-depth investigation
25 of it. What I did note is in one of the -- one

1 WILLIAM J. VIGILANTE, JR.

2 of the emails, if I remember correctly, that
3 were discussing at the time the prime fill
4 anomaly, which they were calling it prior to
5 the temporary blocked vent event, they had
6 noted there was something in the order of -- I
7 can't remember the numbers, but they gave the
8 numbers and then they gave what they thought
9 was a number of reported events based upon the
10 old error code. I think that's the only
11 statistic I've seen in my review of all of the
12 discovery documents and deposition testimony
13 I've looked at.

14 Q. Do you remember what that statistic
15 was, was it a percentage?

16 A. They didn't provide a percentage;
17 they just provided the two numbers. And, of
18 course, if you have the two numbers, you can do
19 the percentage.

20 Q. But you haven't taken an analysis of
21 what the percentage was of prime -- prime fill
22 anomaly events or temporary blocked vents that
23 came into Medtronic?

24 A. I don't know that I specifically did
25 the calculation, but it was something on the

1 WILLIAM J. VIGILANTE, JR.

2 order of less than 1 percent. That's assuming
3 that there were only 90 events reported that
4 year.

5 But, again, they changed the
6 error classification or the classification of
7 the event, and they went from 90 a year to 750
8 a year, so that, of course, would change the
9 percentage. But they didn't provide the -- I
10 didn't see any data of them providing the
11 number of infusion or -- or pump patients.

12 And I don't recall if the number
13 that I did see was pump patients or the number
14 of infusion sets sold in the year. So that
15 would be a different analysis depending upon
16 whether you're looking at patient population or
17 the number of infusion sets sold.

18 Q. So I take it sitting here now you
19 don't have a percentage in your mind of what
20 percentage of prime fill anomaly events or
21 complaints that came in compared to the total
22 number of infusion sets?

23 A. Yeah, I don't know what the exact
24 number is. I do know that more than one was
25 one too many, but I don't know what the exact

1 WILLIAM J. VIGILANTE, JR.

2 number is.

3 Q. Is it your view then that one
4 incident of temporary blocked vent or prime
5 fill anomaly should have initiated action by
6 Medtronic?

7 A. It's my view that they should have
8 identified this before they put this product on
9 the market. And had they, they wouldn't have
10 had one reported incident, and they wouldn't
11 have had one injury or death because of it.

12 Q. Uh-hum.

13 A. This was a foreseeable consequence of
14 the design of that vent system on the top of
15 the P-Cap, and it's something through proper
16 human factors and risk analysis that a prudent
17 manufacturer of Medtronic's -- Medtronic's
18 place would have and should have caught --

19 Q. And --

20 A. -- and addressed.

21 Q. So you -- your opinion is that
22 somewhere in the 2000 time frame Medtronic
23 should have identified this hazard?

24 A. It should have been identified during
25 development.

1 WILLIAM J. VIGILANTE, JR.

2 Q. And I take it then you disagree with
3 Mr. Klimowicz that it would have been difficult
4 to identify a temporary blocked vent as a
5 potential hazard?

6 A. I don't know what Mr. Klimowicz
7 testified to regarding that topic. But it's my
8 opinion that through proper risk and -- excuse
9 me, risk and human factors analysis, this would
10 have been identified during development.

11 Q. So would you disagree that it would
12 have been difficult to identify temporary
13 blocked vent as a potential hazard during
14 development?

15 A. Given the way they designed the
16 product, I would. They didn't have any human
17 factors input into the design until they were
18 looking at the usability, quote/unquote,
19 usability testing of the IFU. At that point
20 you're integrating human factors late into the
21 design process. It should have been up front.

22 As I note in my report, part of
23 the risk assessment should have included a task
24 analysis. And based upon Randy Adair's
25 knowledge regarding what can happen when the

1 WILLIAM J. VIGILANTE, JR.

2 vents were blocked and there was not
3 equalization of the pressure inside the vial
4 and the atmosphere outside, this should have
5 been caught during development had they
6 integrated and conducted proper risk and human
7 factors analysis.

8 Q. Would you agree that if the
9 instructions for use in the Medtronic Getting
10 Started Guide are followed, you would not have
11 a temporary blocked vent occurring?

12 A. Yeah, I don't know that that's the
13 case. And certainly, it depends upon which
14 tradition of the IFU.

15 So if you follow the
16 instructions in the 2000 -- the IFU that was
17 provided with the infusion -- the reservoirs in
18 2013, 2014, in the -- I have to go back and
19 look at the pump manual. But if you follow
20 those two versions of the IFU, your chances of
21 getting insulin squirting onto the reservoir
22 and removing the reservoir from the transfer
23 guard were minimized.

24 But there was still a risk of
25 getting liquid either on the P-Cap or the top

<p style="text-align: right;">Page 114</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 of the reservoir from other sources while doing 3 the infusion set changeover. So it's not just 4 the insulin that could potentially lead to the 5 closed block, it could be any -- any other type 6 of liquid or oil. So it was still possible 7 even if you follow with those IFUs to have the 8 event occur. 9 Q. And so I just want to narrow this a 10 bit. Would you agree that if you follow the 11 instructions for use specifically in the 523 12 insulin pump that the Brackins were provided 13 and relied upon, if they follow the 14 instructions for refilling the reservoir, would 15 you agree that you could not have a temporary 16 blocked vent? 17 MR. HAVERTY: Which 18 instructions? 19 BY MR. MERRELL: 20 Q. Oh, I'm sorry, I'll ask it again if 21 it's not clear. 22 MR. HAVERTY: No, no, because 23 there are several sources for 24 instructions. 25</p>	<p style="text-align: right;">Page 115</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 BY MR. MERRELL: 3 Q. No, I understand. I thought I was 4 being specific, but I'm going to try it again. 5 Would you agree that if the 6 Brackins followed the -- well, I'll tell you 7 what, I'll wait until we get to the Getting 8 Started Guide and it may be easier to do it 9 then. 10 A. Okay. 11 Q. Is it your opinion that Medtronic 12 failed to follow the FDA guidances from 2000 on 13 human factors with respect to the -- the 14 infusion set? 15 A. With respect to the design of the 16 infusion set system, I'm not aware of them 17 conducting any human factors testing or 18 evaluation or analysis. It's not until the 19 usability studies, quote/unquote, were 20 conducted on the IFUs after the product was 21 designed and developed did they implement any 22 type of human factors or usability analysis or 23 evaluation. 24 Q. Do you believe that those usability 25 studies they did on the IFU complied with the</p>
<p style="text-align: right;">Page 116</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 FDA guidance from 2000 on human factors? 3 A. Yes and no. 4 Q. And how did they not comply? 5 A. Well, they were improperly conducted 6 for what they were supposed to be. So 7 conducting the usability studies in and of 8 themselves is a good thing, but the way in 9 which they were conducted, specifically the 10 user population and the fact that they never 11 evaluated the final IFU to validate it, were 12 improper usability methodologies. 13 So they -- it was a good thing 14 that they did the testing, but it was a bad 15 thing that they did it improperly. 16 Q. And is there anything specifically 17 that you cite to in the 2000 guidance as a 18 source for how they should have conducted the 19 usability studies? 20 A. I don't believe I looked or relied 21 upon the 2000 guidelines specifically on how to 22 do the usability studies. 23 I'm relying upon my education, 24 experience and training. If you're going to do 25 usability studies with a product that's going</p>	<p style="text-align: right;">Page 117</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 to be used by a known population, it's 3 appropriate to bring members of that population 4 in to rely upon folks that worked for a company 5 that are aware and -- of -- of the products and 6 had experience with them as opposed to 7 first-time users, that's -- and then try to 8 extrapolate those results to first-time users, 9 it's not proper. 10 So if they were going to do 11 usability studies, they should have brought 12 people in that were potential patients to 13 determine how they responded to the IFUs. And 14 then finally, if you're going to change the IFU 15 based upon your -- your testing, you need to 16 validate it. There was no a validation. 17 There's not even a mention of what was changed 18 from the last time they ran the, quote/unquote, 19 usability study on the IFU. 20 And, again, doing the usability 21 study on the IFU is putting the cart after the 22 horse. Human factors analysis should have been 23 done during the design of that system. 24 The task analysis should have 25 been done before they actually put the parts</p>

1 WILLIAM J. VIGILANTE, JR.
2 together. When prototypes were available, they
3 should have had users coming in to see how they
4 would interact with them way before the IFU is
5 even developed. So, again, that's another part
6 of the usability studies, quote/unquote, that
7 was improper.

8 Q. Would you agree that the 2000 FDA
9 guidance does not say anything about having to
10 use first-time users for the usability study?

11 A. I don't recall whether or not it
12 does. I'd have to read through the entire
13 document.

14 But proper usability testing
15 methodology includes using people
16 representative of the user population. If
17 you're going to do other forms of human factors
18 evaluation such as hallway testing, then it's
19 appropriate to use a convenient sample such as
20 fellow employees or coworkers. But to do
21 usability testing, it needs to be done within
22 users; otherwise, it's not providing you
23 valid -- valid results for its intended
24 purpose.

25 Q. Is there a specific reference in your

1 WILLIAM J. VIGILANTE, JR.
2 references on page 25 of your report that you
3 rely upon regarding that issue?

4 A. I don't know if there is or there is
5 not. But I can tell you based upon my
6 education, experience and training what the
7 proper way to do a usability study is, and it
8 was not done by Medtronic.

9 As I mentioned a little bit
10 earlier, using coworkers or a convenient sample
11 is appropriate for early hallway testing. But
12 the purpose of the usability study is to bring
13 actual end users in to see how they use the
14 product, and that's not what Medtronic did.

15 Q. Is there a specific human factors
16 guidance or literature that you're citing for
17 that point?

18 A. I don't have a specific example
19 offhand. I'm again relying upon my education,
20 experience and training that includes specific
21 guidances, but I don't -- didn't think it was
22 necessary to cite one in this case.

23 The whole purpose of usability
24 studies is to bring the user in. If you're not
25 going to bring the user in, you're going to use

1 WILLIAM J. VIGILANTE, JR.
2 somebody who's not the user. It's not a
3 usability study. It's a fairly simple and
4 basic principle. So I apologize, I didn't
5 think to bring in a specific reference to
6 support it.

7 MR. MERRELL: I'm going to mark
8 as Exhibit 6 the Getting Started Guide
9 that was produced at Brackin's deposition
10 as Brackin-23.

11 - - -
12 (Whereupon, Exhibit 6 was
13 marked for identification.)
14 - - -

15 THE WITNESS: So to update my
16 prior response, the 2016 FDA human factors
17 of medical device does note under actual
18 use testing that, quote, in such a test
19 the test participants should be
20 representative of the actual users, the
21 clinical environment should be
22 representative of the actual use
23 environments, and the testing process
24 should affect the participant's
25 interaction with the device as little as

1 WILLIAM J. VIGILANTE, JR.
2 possible.

3 So that would be one reference
4 to support my opinions regarding whether
5 or not using coworkers and not the end
6 user population as appropriate.

7 BY MR. MERRELL:

8 Q. Okay.

9 A. So, and then on page 21, when they
10 talk about test participants, under section
11 eight human factors validation testing, it
12 notes, quote, the most important consideration
13 for test participants in human factors
14 validation test something that they represent
15 the population of intended users. So I just
16 wanted to clarify that and append that answer.

17 And, I'm sorry, what was your
18 next question?

19 Q. That's okay. Well, I'll follow up on
20 that actually.

21 There was not a question
22 pending, I was just giving you that.

23 You cited that the 2016 FDA
24 guidance on human factors with respect to
25 requiring that you use actual -- or the

Page 122

1 WILLIAM J. VIGILANTE, JR.
2 participants be actual users. You do
3 understand that that -- that came out well
4 after the products were developed here?

5 A. Two things: One, it says that you
6 use people from user population. They don't
7 have to actually be users. So, for example,
8 when you're developing new product, you're not
9 going to have users because the product is not
10 in existence. So you want to bring people in
11 from the user population. Number two, that
12 document is from 2016, but, again, it's just
13 repeating a basic principle of human factors
14 evaluation in usability testing.

15 I can tell you when I was
16 conducting usability testing for the IBM
17 Corporation on products that was designed for
18 both consumer and commercial purposes, if they
19 were not representative of the user population,
20 it was not a usability test. It would fall
21 under the category of hallway testing,
22 convenient sampling testing. Usability testing
23 infers that you're bringing in people from the
24 user population, representatives from the user
25 population.

Page 124

1 WILLIAM J. VIGILANTE, JR.

2 Q. Okay. If you turn to page 57.

3 A. Sure. Okay.

4 Q. Page 57, the title is changing the
5 quick set infusion using a Revel Insulin Pump;
6 do you see that?

7 A. Yes.

8 Q. And does this provide the
9 instructions for changing the infusion set as
10 well as refilling the reservoir?

11 A. Yes. It starts with rewinding the
12 piston in the pump and then filling the
13 reservoir and connecting the reservoir to the
14 infusion set and then it's going to get to
15 inserting the infusion set into the -- the
16 quick set attached to the body.

17 Q. Do you note that at the top of this
18 version, which the Brackins had, it's
19 highlighted at the top, changing the quick
20 set -- infusion set using Revel Insulin Pump?

21 A. Yes.

22 Q. Did you see in the deposition of
23 Kristin Bettis that she wanted to emphasize
24 this for the Brackins?

25 A. That's what she testified to.

Page 123

1 WILLIAM J. VIGILANTE, JR.

2 Q. Okay. In any case, though, the --
3 this citation you make that the usability study
4 should be done on -- in user populations, that
5 was from the 2016 human factors FDA guidance,
6 correct?

7 A. The stuff I quoted was from the 2016
8 guide. As I mentioned, it is consistent with
9 usability and human factors principle going
10 back decades.

11 Q. Okay. I'm going to object after
12 guide as nonresponsive.

13 Okay. I handed you a copy of
14 what marked as Exhibit 6. It's the Getting
15 Started Guide. This is the same Getting
16 Started Guide that was produced at
17 Mr. Brackin's deposition as Brackin-23.

18 I know you reviewed this and
19 this is a source for your opinions, correct?

20 A. I had a copy of the Getting Started
21 Guide that the Brackins had and marked up
22 during their training.

23 I should append that, too. It
24 wasn't just the Brackins who marked it up, it
25 was also the certified trainer, Ms. Bettis.

Page 125

1 WILLIAM J. VIGILANTE, JR.

2 Q. If you look at step eight of the
3 Getting Started Guide, does it instruct the
4 user to flip the vial over so it is now on the
5 bottom?

6 A. It states flip file over so it is now
7 on bottom.

8 Q. And is it directing the patient to
9 have the insulin vial on the bottom and the
10 reservoir on top?

11 A. That's the intent of it.

12 Q. Would you agree with me that if a
13 patient follows the instructions provided here
14 on page 57 through 58 of the Getting Started
15 Guide for the 523 insulin pump, that you would
16 not have a temporary blocked vent?

17 A. No.

18 Q. And why is that?

19 A. Because the contaminate can be
20 something other than the insulin from the
21 insulin vial that could be on the -- that can
22 get on top of the reservoir. And then when the
23 reservoir is connected to the P-Cap, part of
24 the infusion tubing, you have the same effect.

25 Q. Would you agree with me that if a

1 WILLIAM J. VIGILANTE, JR.

2 user follows the instructions provided here on
3 page 57 to 58 of the Getting Started Guide for
4 the insulin pump, that they would not have a
5 temporary blocked vent from insulin being on
6 the P-Cap?

7 A. I don't know that they can say that
8 either. I'm sorry, that was my answer, I don't
9 know that you can say that either.

10 Q. What other source would there be for
11 insulin causing a temporary blocked vent other
12 than -- well, strike that. Let me ask it a
13 different way.

14 What other possibility would
15 there be from a temporary blocked vent from
16 insulin if the procedure is followed?

17 A. It could be that you have some
18 insulin that migrates out of the -- out of the
19 reservoir when you are handling it. It could
20 be that you remove the transfer guard from the
21 insulin, or when you put the insulin vial down,
22 some of it gets on your hands and that you then
23 touch the top of the -- of the reservoir.

24 So I can't say that it
25 eliminates the possibility of insulin

1 WILLIAM J. VIGILANTE, JR.

2 contaminating the top of the reservoir. I
3 think that if you follow the instructions, it
4 minimizes the risk, but it doesn't eliminate
5 it.

6 Q. You would agree that if you follow
7 the instructions here in the Getting Started
8 Guide from page 57 to 58, that it would
9 minimize the risk of having a temporary blocked
10 vent?

11 A. The risk of insulin causing the
12 temporary blocked vent event would be minimized
13 if you follow the instructions at the time that
14 you were doing it.

15 Q. Are you aware of any incidents of a
16 temporary blocked vent where a user followed
17 the instructions provided by Medtronic in the
18 Getting Started Guide?

19 A. Yeah, I don't know that that data is
20 captured, so offhand, I don't know. And what I
21 mean is not captured by Medtronic.

22 Q. With respect to the Getting Started
23 Guide specifically, what are your criticisms
24 with respect to the instructions provided on
25 the refilling process?

1 WILLIAM J. VIGILANTE, JR.

2 A. Well, there's two. One is that it's
3 kind of a broader issue that's related to the
4 Getting Started Guide as well as the IFUs and
5 the pump manual. Your -- Medtronic is relying
6 upon warnings and instructions to mitigate a
7 hazard that should have been fixed in the
8 design of the product. So what happens is, is
9 although a user such as Mr. Brackin, who
10 follows the guide for the first five or six
11 times, goes to training with the certified
12 trainer and is told and learns to do the task
13 correctly, it doesn't guarantee that at some
14 point in the future they may have lapsed or
15 slipped and do it with a vial below the
16 insulin -- or the reservoir below the insulin
17 vial.

18 So, for example, Mr. Curtis
19 again testified that he was trained, aware and
20 experienced in doing this process, but yet in
21 his own testing to try to figure out what was
22 causing the prime fill anomaly, as it was known
23 at the time, did exactly that. He had a slip.
24 He put -- he removed the reservoir from the
25 transfer guard below -- from below the insulin

1 WILLIAM J. VIGILANTE, JR.

2 vial. In fact, he testified that because he
3 was using the green solution, that when he saw
4 the -- the green drops on the top of the
5 reservoir, he couldn't at first understand how
6 it got there. He had to stop and think about
7 what he did to cause it to get there, and then
8 he realized that even though he had known how
9 do it appropriately or the way Medtronic
10 intended or -- or -- or preferred it to be
11 done, that he did it the opposite way.

12 So that's the number one
13 criticisms, is that you're relying upon
14 something that is imperfect, and it's not as
15 reliable as eliminating it through design to
16 address a problem that could have been and
17 should have been addressed through design.

18 The second part that I have more
19 specifically with the Getting Started Guide is
20 that step number eight is not -- there's
21 nothing to emphasize it. So Mr. Brackin and
22 his daughter testified that when they went
23 through training, the fact that the reservoir
24 needed to be on the -- above the insulin vial
25 when removed was not emphasized. There's

1 WILLIAM J. VIGILANTE, JR.
2 nothing in the Getting Started Guide that
3 emphasizes the need to do that. There's no
4 warning at that point in the task to alert the
5 user of the need to do it and the consequences
6 of failing to do it and so forth. So they're
7 -- they're kind of the specific criticisms I
8 have of the Getting Started Guide.

9 Q. Okay. So one is essentially they
10 should have designed around it?

11 A. Absolutely, that's the -- that's the
12 very first problem with -- with relying upon
13 whether it's the Getting Started Guide or the
14 User Guide or the IFUs. You can tell somebody
15 to do it and people are training these things
16 out every two or three days for years, and it
17 takes just one slip, one intention, one
18 hurrying, one distraction, one fatigue, and
19 they don't invert the unit when they remove the
20 insulin -- or the reservoir from the transfer
21 guard, and then they're at risk for a
22 catastrophic injury.

23 You cannot leave the potential
24 for catastrophic injury at that type of -- at
25 that type of risk. You cannot expect or rely

1 WILLIAM J. VIGILANTE, JR.
2 upon the user to be a hundred percent perfect a
3 hundred percent of the time. It's impossible
4 for a user to be a hundred percent perfect a
5 hundred percent of the time. So you would
6 never want to rely on an instruction or a
7 warning when you're going to address a risk
8 particularly with catastrophic consequences
9 when there was a design solution.

10 Q. And as I understand it, you're not
11 providing opinions or analysis as to what the
12 solution should be or alternative design; is
13 that correct?

14 A. I do have opinions on that. Number
15 one, they -- they put in the market, they --
16 Medtronic introduced this P-Cap so that they
17 can market it as being waterproof. They
18 introduced it into the market, and introducing
19 it into the market introduced this hazard that
20 didn't exist before.

21 And then they never market it as
22 waterproof, so the very reason that they put it
23 out they never actually market it for that
24 reason. It was improper just to introduce a
25 product with a risk -- a risk such --

1 WILLIAM J. VIGILANTE, JR.
2 catastrophic risk with no utility. So from a
3 risk benefit utility ratio, you got a
4 tremendous risk with no benefit. That's
5 absolutely improper. So that's number one.

6 Number two is it's my
7 understanding that there were different
8 membranes that could be used. In fact,
9 Medtronic had come up with them, but were
10 delayed in putting them into the -- into the
11 market in 2015, 2016, 2017. Again, they
12 shouldn't have waited 14, 15, 16 years after
13 this product is introduced to getting around to
14 changing the membrane.

15 So they should have looked -- if
16 they were intending on keeping this product in
17 the market, they should have addressed and
18 looked at the membrane back in 1999/2000. So
19 that's my opinions on that topic.

20 Q. And you agree, though, the opinions
21 on the membrane or material, that's not in your
22 expert report?

23 A. It is not.

24 Q. And opinions on alternative design,
25 that's not in your expert report, correct?

1 WILLIAM J. VIGILANTE, JR.

2 A. I do mention the Luer Lock that did
3 not have the hazard in my report. I do note
4 that they never considered alternative
5 materials --

6 Q. Okay.

7 A. -- and alternative designs in my
8 report.

9 I do note that warnings are
10 means of delegating responsibility for product
11 safety to the users in situations where hazards
12 cannot be designed on or so regarded. And I
13 think that's the only areas I address it -- oh,
14 I do address it one more time at the top of
15 section E4 and -- or I note that Medtronic --
16 if Medtronic choose not to design up a hazard,
17 it should have at least provided adequate
18 instructions and warnings with the infusion set
19 and reservoir.

20 Q. But you don't state in your report
21 specific opinion that a specific design should
22 have been implemented?

23 A. I don't provide a specific design
24 other than mentioning the Luer Lock did not
25 have that hazard.

<p style="text-align: right;">Page 134</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Q. Okay. You mentioned that, but you 3 don't -- you don't provide an opinion that they 4 should done a specific design as an 5 alternative? 6 A. Oh, no, I don't. I opined that they 7 should have done the proper risk and human 8 factors analysis and identify the risk and then 9 addressed it appropriately. 10 Q. How should the Getting Started Guide 11 have emphasized the -- the inversion of the 12 insulin vial and the reservoir? 13 A. I noted in my report with the use of 14 arrows to emphasize the flip. This is also 15 consistent with Medtronic's management team's 16 assessment regarding their IFUs that were used 17 back in the 2013 time frame. 18 So on page 22 of my report, I 19 provide those examples. In conjunction with 20 the additional pictograph and arrows, I note 21 that a warning should have been provided 22 consistent with the ANSI C535.6 standard to 23 draw attention to the hazard and how to avoid 24 it and the consequences of not avoiding it. 25 Q. And what would the warning have said?</p>	<p style="text-align: right;">Page 135</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. It's noted on page 23 of my report. 3 I'm happy to read it. 4 Q. Sure. 5 A. It would start with a signal ward of 6 warning with a signal ward header. It would 7 state something on the order of ensure 8 reservoir top and tubing connector were clean 9 and dry. Liquid can block the vents on a 10 tubing connector causing under or 11 overinsulinization delivery, under or 12 overdilution of insulinization can result in 13 severe injury or death. If the connector gets 14 wet, throw infusion set and reservoir away and 15 use new ones. 16 I also note -- so pages 22 and 17 23 of my report provide the alternatives. 18 Q. Do you know whether or not there are 19 any other components of the Getting Started 20 Guide and instructions provided that similarly 21 if not followed could have a potential risk of 22 overdilution of insulin? 23 A. I imagine that there are other parts 24 if not -- if the pump is not used correctly 25 that can result in over or under -- over or</p>
<p style="text-align: right;">Page 136</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 underdelivery of insulin. 3 Q. Do you think that in every instance 4 in the Getting Started Guide if there's a 5 potential -- if the instruction is not followed 6 there's a potential for over or underdelivery 7 of insulin, that it should be noted with a 8 warning? 9 A. Any hazard associated with the use or 10 foreseeable misuse of the product should be 11 noted with a warning if it's not addressed 12 through a design and/or guarding in the manual. 13 Q. So, hypothetically, if there were 50 14 instructions in the Getting Started Guide which 15 if not followed could lead to an overdilution 16 or underdelivery of insulin, should it have a 17 warning that states that? 18 A. I'd have to look at the specific 19 instances. But generally, the user has a right 20 to know that if a specific step, if not done in 21 the manner which was prescribed in the User 22 Guide, can result in significant injury or 23 death, they have a right to know when you do 24 that through a warning. 25 Warnings are designed and</p>	<p style="text-align: right;">Page 137</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 formatted to draw attention, or capture 3 attention, communicate the fact that there is 4 safety information, that there's a safety issue 5 associated with that particular step or task as 6 laid out in the User Guide or Getting Started 7 Guide. 8 Q. And I take it you haven't done an 9 analysis as to whether or not a warning for 10 overdilution or underdelivery of insulin should 11 be included for any other component of the 12 Getting Started Guide? 13 A. Yeah, I did not do an assessment of 14 the entire Getting Started Guide to determine 15 what risks or hazards were with different 16 aspects of the -- of the system and/or use of 17 the system. 18 Q. One of the parts of your task 19 analysis relates to the dominant hand in 20 evaluating the appropriate instructions for 21 use; is that correct? 22 A. It does. I'm sorry, go ahead. 23 Q. How would you -- should the User 24 Guide have differing instructions depending if 25 someone is left or right-handed?</p>

<p style="text-align: right;">Page 138</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. I don't believe so. 3 Q. With respect to the 2014 reservoir 4 guide, you have your opinions on page 14 5 through 15; do you see that? 6 A. Yes. 7 Q. And are those criticisms entirely 8 based on human factors principles of which hand 9 to place the reservoir in? 10 A. In part. 11 Q. And what else is it based upon? 12 A. Well, it's noted above that, starting 13 on page 12 and going from page 12 going into 14 13. 15 Q. Do you believe there should have been 16 any additional warnings on the 2014 reservoir 17 IFU? 18 A. Again, they needed -- Medtronic 19 needed to highlight the inversion or the 20 flipping on the IFUs, and they needed to put a 21 warning at the point where you're going to 22 attach the P-Cap to the top of the reservoir. 23 Q. And the infusion set IFU post-2014, 24 did that need to have a warning as well? 25 A. Same.</p>	<p style="text-align: right;">Page 139</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Q. Would you agree that for any product 3 that's developed that there can be 4 unanticipated risks and hazards that are 5 discovered following the marketing of the 6 product? 7 A. Sure. 8 Q. And would you agree that a risk 9 analysis of any product is not going to be able 10 to identify every possible risk or hazard of a 11 product? 12 A. Sure. 13 Q. Have you ever had any of your 14 opinions excluded in court before? 15 A. Sure. 16 Q. How many times do you think? 17 A. I'm aware of three times I was not 18 allowed to provide testimony at trial. 19 Q. And have there been times when your 20 testimony has been not excluded, but has been 21 limited by a judge? 22 A. Sure. 23 Q. About how many times do you think 24 that's happened? 25 A. I'm aware of two occasions.</p>
<p style="text-align: right;">Page 140</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Q. Have you ever rendered an opinion in 3 a case that the instructions and warnings 4 provided were adequate? 5 A. Yes. 6 Q. How many times have you done that? 7 A. I don't know. 8 Q. Over -- since working with Forensic 9 Consulting -- strike that. 10 Since 2015, with your own 11 company, have you issued any opinions that 12 warnings or instructions for use were adequate? 13 A. I believe so. 14 Q. How many times have you done that? 15 A. I don't know. 16 Q. How many cases do you think you've 17 taken since you started your company in 2015? 18 A. I don't have a number. 19 Q. Do you have an estimate about how 20 many cases you work on as an expert a year? 21 A. I'd say 30 maybe. 22 Q. In the past year, have you issued any 23 opinions that the warnings are -- 24 A. It's probably -- yeah, I'm sorry, 25 it's probably higher than that because I get --</p>	<p style="text-align: right;">Page 141</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 you know, cases tend to back up, so I might 3 have a -- you know, write a report in 2016 and 4 then be deposed in 2018 and go to trial or be 5 deposed in 2017 and go to trial in 2018, so I 6 may be working on a case on different parts 7 over a span of three or four or five years. So 8 it's probably higher than that. 9 Q. Okay. So the number of cases is 10 probably higher than 30? 11 A. That I work on in a year, yes. 12 Q. Did you look at the checklist at all 13 that Ms. Bettis covered with the Brackins as 14 part of her training? 15 A. You're going to have to show it to me 16 and -- 17 MR. MERRELL: I will. That's 18 fine. 19 I'm going to mark as Exhibit 7 20 the Pre-Pump Training Checklist and I'll 21 mark as Exhibit 8 the Pump Start Training 22 Checklist. 23 - - - 24 (Whereupon, Exhibit 7 and 25 Exhibit 8 were marked for</p>

1 WILLIAM J. VIGILANTE, JR.
2 identification.)
3 - - -
4 BY MR. MERRELL:
5 Q. I'll hand this to you, and I have a
6 copy for you.
7 MR. HAVERTY: Okay.
8 BY MR. MERRELL:
9 Q. And looking at Exhibit 7 and 8, have
10 you reviewed these documents before?
11 A. Offhand, I don't know. I'm sorry, I
12 answered only to No. 7. I haven't looked at
13 No. 8.
14 Q. Oh, that's fine. Okay. So we'll
15 just clarify for the record.
16 A. So these two --
17 Q. Offhand, you don't know if you
18 reviewed Exhibit 7, which is the Pre-Pump
19 Training Checklist?
20 A. Did you give me two copies of it?
21 Q. They look very, very similar.
22 Hopefully, I marked them differently.
23 A. One is marked, one is not.
24 Did you give me two pre-pumps?
25 Q. Maybe. I did. All right. Sorry.

1 WILLIAM J. VIGILANTE, JR.
2 didn't follow to make sure that's exactly what
3 it says, but something of that nature.
4 Q. Okay. And this is dated, if you look
5 on the second page, it's dated August 27, 2013?
6 A. Yes.
7 Q. And on that day, did Ms. Bettis, did
8 she spend about three hours with the Brackins
9 training them?
10 A. It appears that way.
11 Q. Did you read the portion of her
12 deposition of Ms. Bettis?
13 A. I did read Mrs. Bettis's testimony.
14 Q. I was trying to ask a question, and I
15 needed water, I hadn't quite finished, my
16 apologies.
17 Did you read the portion of
18 Ms. Bettis's testimony where she said she spent
19 a significant amount of the time in the
20 training addressing the infusion set change and
21 refilling the reservoir?
22 A. I do recall that that topic was
23 addressed in her deposition.
24 You guys want to take five
25 minutes?

1 WILLIAM J. VIGILANTE, JR.
2 Let's fix this.
3 Oh, I see now, I gave you two of
4 those.
5 A. Sorry.
6 Q. So Exhibit 7 is the pre-pump and
7 Exhibit 8, which I gave you previously, is the
8 Pump Training Checklist.
9 A. So looking at Exhibit 7, I don't
10 recall if I've seen it before.
11 Q. And what about Exhibit 8, the Pump
12 Training Checklist, have you seen this one
13 before?
14 A. I don't recall if I've seen this one
15 before either.
16 Q. Okay. If you look at Exhibit 8, the
17 Pump Training Checklist, is one of the items
18 that's checked there, the second from last, the
19 infusion set patient demonstrated the ability
20 to fill reservoir and change infusion set with
21 minimal assistance?
22 A. Are you asking me if that's checked?
23 Q. Yeah, if that's what it says and if
24 it's checked?
25 A. Yes, that's what -- it's checked. I

1 WILLIAM J. VIGILANTE, JR.
2 Q. Yeah, sure.
3 A. Because I've been sitting about an
4 hour.
5 THE VIDEOGRAPHER: We are now
6 going off record. This ends DVD number
7 three. The video time is 1:57.
8 - - -
9 (Whereupon, a short recess
10 was taken.)
11 - - -
12 THE VIDEOGRAPHER: We are now
13 back on record. This begins DVD number
14 four and the video time is 2:09.
15 BY MR. MERRELL:
16 Q. Are there particular Medtronic
17 employees that you're critical of in this case?
18 A. What do you mean?
19 Q. I don't know. Do you have any
20 criticisms of a specific Medtronic employee in
21 this case?
22 A. In what way? I don't think any of
23 them are bad people, so I don't -- I'm not sure
24 what you're asking me.
25 Q. Okay. Would you agree Medtronic is a

<p style="text-align: right;">Page 146</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 good company? 3 MR. HAVERTY: Objection. 4 THE WITNESS: I don't have an 5 opinion on them. Obviously, I'm not aware 6 of -- maybe it's not obvious. But I am 7 not aware of all the different products 8 they sell. 9 BY MR. MERRELL: 10 Q. Okay. 11 A. Or different industries they're in. 12 I'm aware of this particular product in this 13 particular system. 14 Q. Do you have any criticisms of any 15 specific action that a Medtronic employee took 16 in this case? 17 A. Well, for example, Randy Adair, when 18 he was designing the P-Cap, and I do note in my 19 report that he failed to conduct any type of 20 risk or hazard analysis with the design, and 21 that's improper. He was the guy responsible 22 for designing that thing, but yet he designed 23 it in a vacuum with absolutely no consideration 24 for how it would be used and the environments 25 in which it would be used with respect to its</p>	<p style="text-align: right;">Page 147</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 connection to the reservoir and so forth. 3 Q. Do you have any other specific 4 criticisms of any Medtronic employees? 5 A. Not offhand. 6 Q. Let me ask you a couple more 7 questions about your CV. The front of your CV, 8 you have a title page called human factors and 9 ergonomics experience; do you see that? 10 A. Yes. 11 Q. What is the purpose of this 12 particular page of the CV? 13 A. I put it together back in 2003 when I 14 joined Robson Forensic or a -- a version of it 15 back then just to kind give an overview of the 16 different areas in which I apply my expertise 17 in human factors and ergonomics. And then 18 some -- 19 Q. I'm sorry, go ahead. 20 A. Well, I'm sorry. Some of it is also 21 a summary of some of my experience in different 22 areas of the human factors and ergonomics as 23 applied. 24 Q. And one of the areas you have listed 25 here is warnings; do you see that?</p>
<p style="text-align: right;">Page 148</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. Yes. 3 Q. And you have another bullet for 4 vision and driving? 5 A. Yes. 6 Q. Another bullet for motorcycle? 7 A. Yes. 8 Q. Do you have particular expertise with 9 respect to motorcycle human factors issues? 10 A. Yes, I have investigated human 11 factors associated with the performance of 12 motorcycle riders. 13 Q. And do you have significant 14 experience with respect to human factors and 15 ergonomics issues related to vision and 16 driving? 17 A. Yes. 18 Q. What about slip, trips and falls, is 19 that an area you have significant human factors 20 experience in? 21 A. Yes, it was going back to 22 undergraduate and graduate school studying 23 human gait and pedestrian safety whether it be 24 in a work space, work setting, or residential 25 or retail.</p>	<p style="text-align: right;">Page 149</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Q. What about -- 3 A. Public setting. 4 Q. You also list workplace safety as a 5 bullet here? 6 A. Yes. 7 Q. And you list recreational and 8 sporting activities as a bullet? 9 A. Yes. 10 Q. You list lighting as a bullet? 11 A. Yes. 12 Q. And do you have accessibility on here 13 as a bullet? 14 A. Yes. 15 Q. And then, aging, is that another area 16 where you list here in a bullet? 17 A. Yes. 18 Q. And then you list medication labeling 19 as a bullet, too; is that correct? 20 A. Yes. 21 Q. And then you have product design and 22 development as a bullet? 23 A. Yes. 24 Q. And you have user center design as a 25 bullet; is that correct?</p>

<p style="text-align: right;">Page 150</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. Yes. 3 Q. Do you agree with me that on this 4 page of your human factors and ergonomics 5 experience you don't specific list medical 6 devices? 7 A. I don't specifically use that phrase 8 "medical devices". 9 Q. With respect to the medication 10 labeling bullet, what -- what experience 11 specifically are you calling out here? 12 A. So from, I guess, like the mid-90s 13 until 2004/2005 time frame, I was involved in 14 research -- researching factors that affect the 15 adequacy of medication labeling for both 16 prescription -- excuse me, nonprescription 17 labeling and prescription medication 18 advertising. So that would be what I'm 19 referring to -- 20 Q. Okay. 21 A. -- with that statement. 22 Q. So the reference here, the bullet for 23 medication labeling, this is in the 2004 and 24 2005 time frame -- I apologize, I was 25 misreading that. I'll rephrase it.</p>	<p style="text-align: right;">Page 151</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 The medication labeling bullet 3 you have here is from the mid-1990s to the 2004 4 and 2005 time frame? 5 A. That's when I was doing 6 approximately -- I guess it's probably more 7 closer to '95 to about 2004/2005. I was active 8 in research related to medication -- 9 over-the-counter medication labeling and 10 prescription medication advertising. 11 Q. And what were the -- were there 12 specific aspects of the labeling that you 13 worked on? 14 A. Yes. So back in the mid to late '90s 15 under grants from the Drug Information 16 Association and in cooperation with the FDA, 17 our lab, generally and myself specifically 18 conducted a number of research studies the 19 factors that affect the adequacy of over -- 20 over-the-counter medication labeling for both 21 adults and older adults. Older adults were 22 specific population of interest. We looked at 23 things as to how to present information on the 24 labels, how to order the information, the 25 effect of font size, information gathering,</p>
<p style="text-align: right;">Page 152</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 effect of light spacing, and other formatting 3 features. 4 The work that was done and 5 published was used by the FDA when they 6 promulgated their over-the-counter medication 7 labeling regulations in 1999. So a lot of that 8 regulation -- of lot of those regulations were 9 a direct result of the findings from both my 10 research specifically and our lab's research 11 more generally. 12 Once that project was done or 13 those -- those series of projects were done, I 14 personally went back to my contacts at the FDA 15 to inquire as to what other areas they foresaw 16 the need for human factors-type research. 17 And -- and the big area that they identified 18 was the advertising of prescription 19 medications, which shortly before the late 20 1990s the government changed their laws 21 allowing pharmaceutical -- pharmaceutical 22 companies more -- giving them more ability to 23 advertise directly to consumers whether it be 24 television, magazines, newspapers or on the 25 World Wide Web.</p>	<p style="text-align: right;">Page 153</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 So both, again, myself 3 specifically and the lab generally conducted 4 another series of projects looking at how to 5 present both benefit and risk information and 6 prescription medication advertisements. Again, 7 our research was fed back into the FDA to help 8 them update and improve the regulations to 9 ensure that consumers were getting a fair 10 balance between the risks associated with a 11 particular medication to the benefits that the 12 medication offered. 13 Q. Did you do any work in terms of the 14 language of warnings with respect to the 15 medication guide -- or the medication labeling? 16 A. I don't remember doing anything 17 specifically with specific language in that 18 time frame. 19 Q. Did you ever write the labeling or 20 warnings for a medication? 21 A. I did create different medication 22 labels for multiple different studies that were 23 conducted. Is that what you're asking me, or 24 are you asking me -- 25 Q. Describe that for me. The medication</p>

Page 154

1 WILLIAM J. VIGILANTE, JR.

2 label for the studies, was it for the study or
3 for the actual final labeling of the drug?

4 A. Well, no. So during the studies,
5 some of the usability studies using actual
6 representatives from the user population, we
7 mocked up containers of over-the-counter
8 medications and mocked up the labels for those
9 containers and then used those labels and
10 containers in the actual studies.

11 The work that we were doing was
12 not specific for a single drug or a single
13 manufacturer, it was for the regulations. So
14 when you go into the over-the-counter
15 medication labeling regulations and they state,
16 there's a minimum font size, a certain type of
17 formatting, the need for bordering and
18 categorization of the information, the need for
19 ordering the information in a certain order on
20 the label, those requirements are based upon
21 the research findings in part from my work and
22 the work done as others in our lab. So it
23 wasn't for a specific manufacturer or specific
24 drug, it was for regulations in general.

25 Q. Were these medication labels that

Page 155

1 WILLIAM J. VIGILANTE, JR.

2 you -- that you mocked up, were these for an
3 actual drug or was it a placebo? I'm just
4 trying to understand.

5 A. Yeah, we used -- we didn't take,
6 like, for example, in my doctoral thesis or
7 doctoral dissertation, when I was dealing with
8 prescription medication advertisements, I used
9 actual drugs and the information from those
10 drugs and manipulated how it was presented.
11 For the over-the-counter stuff, I think we used
12 the labeling information; so, for example, the
13 ingredients, the directions for use, the
14 warnings and side effects from an existing
15 medication or medications, but changed the name
16 of them so we wouldn't put out a brand name
17 like Tylenol.

18 You know, we would create a
19 fictitious name, but use the information from,
20 you know, an existing medication or label to
21 create our labels.

22 Q. Let's take a look at back to your CV.
23 The workshops and continuing education.

24 A. Okay.

25 Q. Do any of the workshops and

Page 156

1 WILLIAM J. VIGILANTE, JR.

2 continuing education you list here relate to
3 medical devices?

4 A. They do.

5 Q. Which ones?

6 A. So, for example, risk assessment in
7 human reliability, some practical tools for
8 improving safety and human factors approach to
9 accident analysis and prevention, there were
10 workshops that covered basic -- or different
11 human factors and risk assessment principles
12 and how to apply them to different -- different
13 systems.

14 Q. Were medical devices specifically
15 addressed at that workshop?

16 A. I don't recall them specifically
17 addressing medical devices during the
18 workshops.

19 Q. Can you recall medical devices being
20 addressed at any of the workshops that are
21 listed here?

22 A. I don't think the other workshops
23 would be relevant to design medical devices.

24 Q. Taking a look at your certifications,
25 you have an IPAF operator training

Page 157

1 WILLIAM J. VIGILANTE, JR.

2 certification?

3 A. Yes.

4 Q. What is that?

5 A. That's the International Powered
6 Access Federation. So it's training for crane
7 operation -- or, sorry, lift operation.

8 Q. Then you have the Raymond Safety on
9 the Move forklift certification?

10 A. Yes.

11 Q. What is that?

12 A. Again, it's certification for
13 forklift operation.

14 Q. Then you have a fire con safety
15 emergency response training as well?

16 A. Yes.

17 Q. And what is that?

18 A. That was safety training for confined
19 space entry.

20 Q. And then you have Motorcycle Safety
21 Foundation, a basic rider course and
22 off-highway motorcycle course?

23 A. Yes.

24 Q. What is that exactly?

25 A. There are two different courses that

1 WILLIAM J. VIGILANTE, JR.
2 are offered by the Motorcycle Safety
3 Foundation. One was for basic rider courses,
4 essentially for street riding. The other one
5 was for off-road motorcycle riding. So there's
6 safety courses for those two different
7 activities.

8 Q. Do you ride motorcycles?

9 A. I do.

10 Q. That's the most important question of
11 the deposition.

12 Did you take these courses
13 primarily for your own interest or is it also
14 part of your professional experience?

15 A. Both.

16 Q. And you have a bullet here for
17 National Rifle Association instructor
18 certification for certified rifle?

19 A. Yes.

20 Q. And there's also a certified pistol
21 personal protection at home and personal
22 protection outside the home?

23 A. Yes.

24 Q. Does that also relate to your
25 professional work?

1 WILLIAM J. VIGILANTE, JR.

2 A. I don't do a whole lot of firearm
3 safety. I've done some over the years. It's
4 certainly an area that I would be happy to do
5 work in.

6 Q. Are any of your certifications
7 related to medical devices?

8 A. Not that I'm aware of.

9 Q. And then you have professional
10 memberships and affiliations. You're a member
11 of the American Society of Safety Engineers?

12 A. Yes.

13 Q. You're a member of the Human Factors
14 and Ergonomics Society?

15 A. Yes. That needs to be updated.

16 Q. How so?

17 A. I'm the current program chair for the
18 product technical group.

19 Q. You're also a member of the
20 Illuminating Engineering Society?

21 A. Yes.

22 Q. What is that?

23 A. It's the Illuminating Engineering
24 Society of North America. So it's
25 professionals that are involved in the field of

1 WILLIAM J. VIGILANTE, JR.
2 lighting, artificial lighting, so whether it be
3 workspace, workstation lighting, roadway
4 lighting, et cetera.

5 Q. Okay. And then you have a number of
6 publications and presentations here that are
7 listed on your CV?

8 A. Yes.

9 Q. Do any of these publications or
10 presentations deal specifically with medical
11 devices?

12 A. I don't think that any of them deal
13 specifically with medical devices. Some of
14 them deal with over-the-counter medication
15 labeling, some of them deal with prescription
16 medication labeling.

17 Q. Okay. And then you have a section
18 called technical reports?

19 A. Yes.

20 Q. Are these primarily technical reports
21 from your work at IBM?

22 A. They're exclusively technical reports
23 from my work at IBM.

24 Q. And I take it none of these technical
25 report relate to medical devices?

1 WILLIAM J. VIGILANTE, JR.

2 A. There were no specific medical
3 devices. I can't say that they don't relate to
4 them because there's some -- some technical
5 reports on, for example, the comparison of
6 usability testing methodologies, which would be
7 applicable to the design of medical devices,
8 but it wasn't specific to medical devices.

9 Q. Okay. And then you have a list of
10 published patents as well?

11 A. Yes.

12 Q. And none of the patents are for a
13 medical device or components of a medical
14 device?

15 A. I'll agree with the first one. The
16 second one, I can't say that it's not because
17 there are medical devices that use wireless
18 technology, so I can't say that not.

19 Q. So you agree there's not a patent for
20 a medical device?

21 A. None of them include a patent for a
22 specific medical device.

23 Q. And you don't know whether or not one
24 might be a component in a medical device?

25 A. I don't know if one might be related

<p style="text-align: right;">Page 162</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 or relevant to a medical device. 3 Q. You said you read the deposition of 4 Rita Weaver? 5 A. Yes. 6 Q. Was there anything specific in that 7 deposition that's germane to your warnings or 8 labeling opinions? 9 A. I'm not recall anything specific 10 offhand, and I don't think I specifically 11 reference her in my report. 12 Q. Did you assess at all in your report 13 the warnings or information provided to 14 Ms. Weaver? 15 A. One more time. 16 Q. Did you assess at all in your report 17 the warnings or information provided by 18 Medtronic to Ms. Weaver? 19 A. I don't think I looked at any 20 instructions or manuals that were provided to 21 Ms. Weaver that was not provided to the 22 Brackins or related to the pump, the infusion 23 set or the reservoir. 24 Q. And you haven't provided any opinions 25 in your report as to whether or not Rita Goidel</p>	<p style="text-align: right;">Page 163</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Weaver was adequately informed or warned 3 regarding the Medtronic insulin pump reservoir 4 or infusion set? 5 A. I do not address that in my report. 6 Q. And you don't address in your report 7 any of the information that Ms. Weaver may have 8 provided to the Brackins with respect to 9 warnings and instructions for the insulin pump 10 infusion set or reservoir? 11 A. I don't recall her providing the 12 Brackins with any instruction or warning 13 related to this issue or the issue that I'm 14 addressing in my report. 15 Q. By that, you mean a temporary blocked 16 vent? 17 A. Yes, or the necessity of ensuring the 18 reservoir was on top of the insulin vial when 19 removing it. 20 Q. You have a reference in the available 21 materials the Urgent Medical Device Safety 22 Notification from June 7, 2013. 23 A. You said available material? 24 Q. Yes. 25 A. All right. One more time, Urgent</p>
<p style="text-align: right;">Page 164</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Medical Device Safety Notification? 3 Q. Yes, it's referenced in the available 4 materials. 5 A. Yes. 6 Q. Is that something you reviewed? 7 A. Yes. 8 Q. Did you make any analysis or 9 assessment of the adequacy of that 10 notification? 11 A. I did not. I'm not aware of the 12 Brackins receiving the dear patient letter. 13 Q. If they didn't receive it, would it 14 not be relevant to your analysis? 15 A. Yes and no. 16 Q. But in any case, you didn't assess it 17 for adequacy in your report? 18 A. I didn't assess the dear patient 19 letter for adequacy as the notification of the 20 problem or issue to patients. 21 What I would have used it was -- 22 what I would have used it for was again the 23 background information of Medtronic's 24 recognition of the issue and what was required 25 to emphasize to the user and what they needed</p>	<p style="text-align: right;">Page 165</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 to be informed about. So that would have been 3 how I used that document. 4 Q. And you haven't done an assessment of 5 Medtronic's CAPA investigation and response to 6 the temporary blocked vent issue they 7 discovered in 2012 to provide opinions in your 8 report? 9 A. I don't have opinions in my report of 10 Medtronic's CAPA response. 11 Q. And you're not providing any opinions 12 about whether or not Medtronic complied with 13 any specific FDA regulations with respect to 14 the labeling or design of the insulin pump, 15 reservoir or infusion set? 16 A. Yeah, I wasn't asked to or planning 17 to provide any opinions regarding Medtronic's 18 compliance to FDA regulations. 19 Q. As I understand it, your focus has 20 been primarily on the industry standards that 21 are not FDA related in terms of your analysis 22 of human factors issues? 23 A. I would state that they're not FDA 24 specific with regard to the issues I was 25 addressing. I think that's the appropriate way</p>

<p style="text-align: right;">Page 166</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 to state it. 3 Q. Are any of the guidances that you're 4 relying upon, other than the 2000 and 2016 5 human factors FDA guidances, are any of them 6 specifically related to medical devices? 7 A. Are you asking me if the specific 8 references I cited in the report; is that what 9 you're referring to? 10 Q. Let's do it a different way. Let's 11 look at the references that are on page 25 of 12 your report. 13 A. Sure, give me one second. 14 Okay. 15 Q. In coming to your opinion, are these 16 the primary references you're utilizing in 17 assessing whether or not Medtronic complied 18 with human factors, principles and industry 19 standards? 20 MR. HAVERTY: Objection. Asked 21 and answered. 22 THE WITNESS: There are specific 23 references that I'm using to support my 24 opinions. 25</p>	<p style="text-align: right;">Page 167</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 BY MR. MERRELL: 3 Q. Okay. And if you look at number 4 four, that's the FDA 2000 guidance, and that 5 does deal specifically with medical devices, 6 correct? 7 A. That is a document titled guidance 8 for industry and FDA reviewers on medical 9 device use. 10 Q. And then you have, for example, a 11 reference to number seven, Wagner 1992, risk 12 taking and accident causation? 13 A. Yes. 14 Q. Outside of the reference number four, 15 do any of the other ten references here deal 16 specifically with medical devices? 17 A. No, they're not limited -- or they're 18 not limited specifically to medical devices. 19 They are references related to the design and 20 development of any and all products and systems 21 that are used by people. 22 So the warnings, references on 23 how to design and development warnings, it's 24 for the design and development of product 25 warnings not specific or limited to a specific</p>
<p style="text-align: right;">Page 168</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 subset of products. The human factors and 3 safety guidelines are for product and 4 development for all products and systems not 5 limited to a specific subset or subtype of 6 product or system. 7 Q. So references one through three and 8 then four through 11 which you rely upon, those 9 are assessing or addressing human factors 10 design principles generally for all types of 11 products? 12 A. Yes, I think it's one to three and 13 then five through 11. 14 Q. Okay. 15 A. Because the four was the FDA that was 16 specifically -- 17 Q. Oh, sorry, I didn't mean to say four. 18 So numbers one through three and then five 19 through 11 deal with human factors principles 20 for all products generally? 21 A. Products and systems, yes. 22 Q. Did you look for any other potential 23 human factors guidances or industry standards 24 that are specific to medical devices other than 25 this number four and the 2016 guidance?</p>	<p style="text-align: right;">Page 169</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. I did not. 3 Q. Did you look to see if there are any 4 ANSI guidances with respect to medical devices 5 specifically? 6 A. I'm not aware of any that were 7 specific or relevant to what I was doing. 8 Q. Okay. And did you look at any 9 specific industry standards, ISO standards or 10 any kind of standard that were specific for 11 risk assessment of a medical device in coming 12 to your opinions? 13 A. I'm not familiar with an ISO standard 14 specific for risk assessment of medical 15 products. I am familiar with ISO standards for 16 risk assessment in general, but not for medical 17 products. 18 Q. You haven't listed any ISO standards 19 on risk assessment, though? 20 A. I do not. 21 Q. Are there any that you rely upon in 22 coming to your opinions here? 23 A. Well, yes and no. Again, as part of 24 my general education, experience and training 25 I'm well aware of both ANSI and ISO standards</p>

<p style="text-align: right;">Page 170</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 for risk -- risk assessment, but I didn't feel 3 the need to specifically reference them in the 4 report. 5 Q. Are you citing to any particular ISO 6 standard that Medtronic did not comply with in 7 assessing the risk and hazard associated with 8 the products at issue here? 9 A. I did not cite an ISO standard in my 10 report. 11 Q. Have you told me today and what's 12 contained in your report -- well, strike that. 13 What's contained in your report, 14 does this contain the sum of your opinions in 15 this case? 16 A. As I planned them as of this morning. 17 So I think what I mean by that is, I think we 18 talked about other areas that may not have been 19 discussed specifically in the report. So I do 20 hold whatever we talked about in our deposition 21 today as opinions as well as what's in my 22 report. 23 Q. Okay. But you haven't prepared any 24 supplemental report for any additional 25 opinions?</p>	<p style="text-align: right;">Page 171</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 A. I have not. 3 Q. And have you provided all the 4 underlying information for your opinions in 5 your report either in your report or in your 6 testimony today? 7 A. I tried to. 8 MR. MERRELL: Okay. I don't 9 think I have any further questions. 10 Do you have any? 11 MR. HAVERTY: Yeah, I just have 12 a couple just real quickly. 13 - - - 14 E X A M I N A T I O N 15 - - - 16 BY MR. HAVERTY: 17 Q. Dr. Vigilante, I don't want to 18 belabor this too much, but we've been here 19 going at this for a few hours now. But could 20 you please give us the benefit -- could you 21 tell us, please, a little bit about the field 22 of human factors involves. 23 A. Sure. I do address what the field is 24 in my report. But human factors is an applied 25 science. And what I mean by that is that from</p>
<p style="text-align: right;">Page 172</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 a basic science standpoint, human factors 3 professionals, researchers, conduct research, 4 things related to, for example, how people 5 gather information through their senses, 6 through whether it's sight, hearing, tactile, 7 et cetera. 8 We look and study how people 9 process information; that is, how they make 10 decisions, how they store information into 11 long-term memory, how information is 12 transitioned into and out of short-term memory. 13 We look at how people's experiences, their 14 attitudes and beliefs, affect how they make 15 decisions and how they perceive risks and so 16 forth. 17 We also look at what we call 18 physical ergonomics; that is, how the body 19 moves, muscle strength, flexibility. I think I 20 mentioned human gait earlier in the deposition. 21 So these are all different topics that from a 22 basic standpoint human factors professionals 23 study. We take that information that we learn 24 through basic science and we apply it to the 25 design of products and systems.</p>	<p style="text-align: right;">Page 173</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 So typically, human factors 3 professionals -- for example, when I was with 4 IBM, I would work with engineers, I'd work with 5 designers, whether they're graphic designers, 6 information designers, industrial designers, 7 mechanical engineers, electrical engineers, et 8 cetera, to design products. 9 So what we're trying to do is 10 apply all of the stuff that we know about how 11 people gather information, how they make 12 decisions, the types of things that cause 13 people to make mistakes or forget things. 14 We take that information and we 15 apply to design. And the goal is to design 16 systems that are easy to use, that are 17 comfortable to use and that are safe. 18 Essentially, what we want to do is design for 19 human use, and human use includes all of our 20 abilities as well as all of our limitations. 21 So I think that's a general description of the 22 field of human factors. 23 Q. And you were asked a number of 24 questions about whether or not you had any 25 involvement in these types of design defects --</p>

<p style="text-align: right;">Page 174</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 design concepts from a human factors 3 perspective as it relates to medical devices; 4 do you recall that? 5 A. Yes. 6 Q. Is there anything that's unique about 7 medical devices as to opposed to any other 8 product that humans might use or interact with 9 that would pose different human factor-type of 10 analysis than, say, a computer keyboard or a 11 cell phone or any other type of product? 12 A. The basic human factors principles 13 and techniques apply regardless of the system 14 or the product whether it's a medical device, a 15 vehicle, workplace equipment, consumer product, 16 et cetera. 17 Q. These are -- these are broadly 18 applicable concepts and principles that you 19 apply across all product lines and subproduct 20 lines? 21 A. Yes, these are basic human factors 22 principles and analysis techniques that are 23 applicable to all system and product design. 24 Q. And did you apply those same types of 25 techniques and that same type of methodology in</p>	<p style="text-align: right;">Page 175</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 human factors that you apply to other types of 3 products in this particular case? 4 A. I did. 5 MR. HAVERTY: Okay. That's all 6 I have. Thanks. 7 - - - 8 E X A M I N A T I O N 9 - - - 10 BY MR. MERRELL: 11 Q. Do you have any experience in 12 academics teaching human factors principles? 13 A. Other than subbing in for professors 14 that were on vacation, I don't think so. I was 15 not an associate or adjunct professor like 16 that. At undergraduate, I taught research 17 methods labs, and I think that's probably the 18 extent of my teaching experience. 19 Q. Okay. About how many times do you 20 think you subbed in for a professor to teach? 21 A. I think it's probably a handful. 22 Q. Have you ever -- do you have any 23 experience conducting failure modes and effects 24 analysis for a device, a product? 25 A. I do. I'm sorry?</p>
<p style="text-align: right;">Page 176</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 Q. You do? 3 A. Yes. 4 Q. How many times have you put something 5 like that together? 6 A. I don't know. I can't give you a 7 number. I can tell you my experience at IBM is 8 that I would be responsible for the total FMEA 9 that was conducted on the products. I would be 10 responsible of inputting into the FMEA that was 11 done. 12 Q. And I take it, though, you've never 13 done an F-M-E-A for a medical device? 14 A. Outside of the Dennert and Brackin, I 15 have not. 16 Q. Have you actually done an F-M-E-A in 17 this case? 18 A. Well, part of the task analysis gets 19 into the failure effect modes analysis. So, 20 for example, for the failure mode and effects 21 analysis you're looking at different aspects of 22 the design where an error or problem in a 23 specific component can result in what type 24 of -- what type of hazards it can result in and 25 how it can -- how it could come about. So a</p>	<p style="text-align: right;">Page 177</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 lot of task analysis information related to 3 types of errors and hazards that are a result 4 of those errors are typically fed back into a 5 larger FMEA. 6 Q. And in this case, you've looked at a 7 specific issue with respect to the F-M-E-A and 8 that's the TBV? 9 I'll just say it again. 10 A. Oh, I'm sorry. 11 Q. In this case, you looked at the 12 F-M-E-A or the D-F-M-E-A analysis you've done 13 in this case is specific to temporary blocked 14 vent? 15 A. Yes, my analysis was focused on the 16 temporary blocked vent event. 17 Q. Did you review the entire D-F-M-E-A 18 for the products at issue here? 19 A. I did not. 20 Q. Did you do a full D-F-M-E-A analysis 21 of all potential risks and hazards -- 22 A. I did not. 23 Q. -- all those products? 24 A. Sorry. I did not. 25 Q. And you've never conducted that sort</p>

<p style="text-align: right;">Page 178</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 of analysis for a medical device? 3 A. A total? 4 Q. Correct. 5 A. I have not. 6 Q. Your only experience with a D-F-M-E-A 7 in litigation in this case and then the Dennert 8 case? 9 A. Well, no. Again, through my work 10 with IBM, it was part of my responsibilities to 11 feed into the overall failure modes, effects 12 analysis and the other parts of the hazard 13 analysis that were done. 14 Q. But you've never done a D-F-M-E-A for 15 a medical device or any sort of analysis like 16 that outside of your work in litigation of the 17 Dennert case and the Brackin case? 18 A. Not that I'm aware of. 19 Q. You mentioned that a medical device 20 isn't really any -- there's nothing unique 21 about a medical device compared to other 22 potential products for assessing from a human 23 factors perspective; is that about right? 24 A. Correct. 25 Q. Wouldn't you agree that there is</p>	<p style="text-align: right;">Page 179</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 something unique about a medical device in that 3 many of them are implanted into the human body 4 and many of them such as this one are actually 5 infusing medication into the human body? 6 A. I agree that medical devices can -- 7 some medical devices are implanted in the human 8 body and some of them infuse drugs into the 9 human body. But from a design perspective, 10 there's got to be a user involved at some 11 point, and human factors is studying that user 12 interaction, so the same principles, basic 13 principles, analysis apply. 14 MR. HAVERTY: Okay. No further 15 questions. 16 - - - 17 E X A M I N A T I O N 18 - - - 19 BY MR. HAVERTY: 20 Q. Just real quickly. 21 Dr. Vigilante, you were asked 22 questions about failure modes and effect 23 analysis. Again, are the concepts of how to -- 24 how to do a failure mode and effects analysis 25 general concepts that are applicable across all</p>
<p style="text-align: right;">Page 180</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 types of products? 3 A. Yes. 4 Q. And it's not -- there's nothing 5 specific or unique about a failure modes and 6 effects analysis as it applies to a medical 7 device as opposed to an automobile or any other 8 type of product, right? 9 A. No. 10 MR. HAVERTY: Okay. 11 - - - 12 E X A M I N A T I O N 13 - - - 14 BY MR. MERRELL: 15 Q. Do you know what ISO standards apply 16 to a failure modes and effects analysis for a 17 medical device? 18 A. Not offhand. 19 Q. Are you aware of any unique ISO 20 standards with respect to the failure modes and 21 effects analysis for a medical device? 22 A. Not offhand. 23 MR. MERRELL: Okay. No further 24 questions. 25 MR. HAVERTY: That's all. We're</p>	<p style="text-align: right;">Page 181</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 done. 3 THE VIDEOGRAPHER: This ends DVD 4 number four. The video time is now 2:49. 5 This ends the deposition today. We are 6 now going off record. 7 THE COURT REPORTER: Can you 8 confirm for the record that you want a 9 rough draft and a regular final. 10 MR. HAVERTY: Yes, please. 11 THE COURT REPORTER: And you 12 want a rough draft and immediate final. 13 MR. MERRELL: Yes, thanks. 14 - - - 15 (Whereupon, the deposition 16 was concluded at 2:47 p.m.) 17 - - - 18 19 20 21 22 23 24 25</p>

<p style="text-align: right;">Page 182</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 I N D E X 3 WITNESS: PAGE 4 WILLIAM J. VIGILANTE, JR. 5 BY MR. MERRELL 4,175,180 6 BY MR. HAVERTY 171,179 7 - - - 8 E X H I B I T S 9 NUMBER DESCRIPTION PAGE 10 Exhibit 1 Notice of Videotape 6 11 Deposition 12 Exhibit 2 CD 9 13 Exhibit 3 Curriculum Vitae 10 14 Exhibit 4 July 31, 2018 Letter 23 15 Exhibit 5 Expert Report 28 16 Exhibit 6 Getting Started Guide 120 17 Exhibit 7 Pre-Pump Training 141 18 Checklist 19 Exhibit 8 Pump Start Training 141 20 Checklist 21 22 23 24 25</p>	<p style="text-align: right;">Page 183</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 CERTIFICATE 3 I HEREBY CERTIFY that the 4 proceedings, evidence and objections are 5 contained fully and accurately in the 6 stenographic notes taken by me upon the 7 deposition of WILLIAM J. VIGILANTE, JR. 8 taken on September 14, 2018 and that this 9 is a true and correct transcript of same. 10 Dated: September 14, 2018 11 12 13 14 _____ 15 Jennifer Miller, RPR and 16 Notary Public 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 184</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 NAME OF CASE: 3 NAME OF WITNESS: 4 Reason Codes: 5 1. To clarify the record. 6 2. To conform to the facts. 7 3. To correct transcription errors. 8 Page _____ Line _____ Reason _____ 9 From _____ to _____ 10 Page _____ Line _____ Reason _____ 11 From _____ to _____ 12 Page _____ Line _____ Reason _____ 13 From _____ to _____ 14 Page _____ Line _____ Reason _____ 15 From _____ to _____ 16 Page _____ Line _____ Reason _____ 17 From _____ to _____ 18 Page _____ Line _____ Reason _____ 19 From _____ to _____ 20 Page _____ Line _____ Reason _____ 21 From _____ to _____ 22 Page _____ Line _____ Reason _____ 23 From _____ to _____ 24 25 _____</p>	<p style="text-align: right;">Page 185</p> <p>1 WILLIAM J. VIGILANTE, JR. 2 I have inspected and read my 3 deposition as captioned above and have 4 listed all changes and corrections above, 5 along with my reasons therefore. 6 7 DATE: _____ 8 9 SIGNATURE OF DEPONENT: _____ 10 11 I have read the foregoing transcript 12 of my deposition and it is true, correct 13 and complete, to the best of my knowledge, 14 recollection and belief, except for the 15 corrections noted hereon and/or list of 16 corrections, if any, attached on a separate 17 sheet herewith. 18 19 _____ 20 WILLIAM J. VIGILANTE, JR. 21 22 Subscribed and sworn to before me 23 this ____ day of _____, 2018. 24 _____ 25 Notary Public</p>

A				
\$495 (1) 35:13	7:6,19	ago (1) 40:17	61:14,17,20 62:24	appear (3) 12:24 60:2 71:7
A-R-C-C-A (2) 39:25 40:3	additional (5) 7:22 27:15 134:20 138:16 170:24	agree (31) 64:14 74:23 85:16 87:8,19 88:5,23 89:10 96:6 99:5,16 99:20 102:18 104:13 113:8 114:10,15 115:5 118:8 125:12,25 127:6 132:20 139:2 139:8 145:25 150:3 161:15,19 178:25 179:6	63:9 64:18 66:21 67:20 72:12,15 73:4 73:24 78:11 79:8,10 80:21 81:9 82:17,25 82:25 83:4,10 84:8 84:12 85:10,12 92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	appeared (1) 106:16
a.m (1) 1:18	address (18) 14:11,18 28:16 49:13 50:3,6,12 54:14 65:14,17 84:15 129:16 131:7 133:13,14 163:5,6 171:23	agreed (1) 14:12	80:21 81:9 82:17,25 82:25 83:4,10 84:8 84:12 85:10,12 92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	appears (2) 10:19 144:10
abilities (1) 173:20	addressed (12) 17:18 65:18,20,22 111:20 129:17 132:17 134:9 136:11 144:23 156:15,20	ahead (6) 5:23 10:11 48:8 80:4 137:22 147:19	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	append (3) 20:10 121:16 123:23
ability (4) 74:25 88:24 143:19 152:22	addressing (13) 20:15 33:14 49:14 50:6 55:16,18,19 83:23 144:20 156:17 163:14 165:25 168:9	al (3) 1:9 3:6,6	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	applicable (4) 161:7 174:18,23 179:25
able (8) 11:9 76:17 82:4 88:6 88:13 89:5 96:7 139:9	adequacy (5) 150:15 151:19 164:9 164:17,19	Aleksandrovich (1) 8:14	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	application (2) 46:24 59:11
absence (3) 76:21,24 77:2	adequate (9) 14:20,24 15:6 17:16 79:19 81:10 133:17 140:4,12	alert (1) 130:4	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	applied (5) 47:12 59:15,18 147:23 171:24
absolutely (5) 41:4 50:17 130:11 132:5 146:23	adequately (1) 163:2	allowed (2) 54:18 139:18	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	applies (1) 180:6
academics (1) 175:12	adjunct (1) 175:15	allowing (1) 152:21	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	apply (13) 47:18 60:12 147:16 156:12 172:24 173:10,15 174:13 174:19,24 175:2 179:13 180:15
access (3) 9:18 11:10 157:6	administering (1) 69:10	alter (1) 27:25	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	applying (3) 13:4 14:10 95:6
accessibility (1) 149:12	adults (3) 151:21,21,21	alternative (18) 17:22 55:5,8,12,13,17 83:23 84:4,8,11,13 84:14 85:5 131:12 132:24 133:4,7 134:5	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	appreciated (1) 90:11
accident (2) 156:9 167:12	advertise (1) 152:23	alternatives (3) 55:9 86:8 135:17	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	approach (1) 156:8
accurate (9) 24:15 25:7 35:15 42:20 55:22 61:8 62:25 101:10,23	advertisements (2) 153:6 155:8	amend (2) 43:18 88:10	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	appropriately (2) 129:9 134:9
accurately (1) 183:5	advertising (4) 44:23 150:18 151:10 152:18	America (1) 159:24	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	approval (1) 47:4
action (2) 111:5 146:15	affect (4) 120:24 150:14 151:19 172:14	American (1) 159:11	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	approved (3) 62:2,11,11
actions (1) 79:14	affidavit (1) 8:21	amount (11) 24:22 30:23 33:16 38:7 72:10,18,22 73:12,23 74:3 144:19	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	approximate (2) 21:24 39:10
active (1) 151:7	affiliations (1) 159:10	analysis (85) 14:21 15:25 45:19,22 45:23 47:8,13,19 50:9 55:25 61:3,6	92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	approximately (7) 3:13 38:12,13,19 41:9 42:6 151:6
activities (3) 24:18 149:8 158:7	Afshin (2) 29:11 70:17		92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	ARCCA (8) 40:3,5,10,15,24 41:11 41:14,16
actual (14) 68:7 75:19 82:5 119:13 120:17,20 120:22 121:25 122:2 154:3,5,10 155:3,9	aging (1) 149:15		92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	area (6) 38:18,24 148:19 149:15 152:17 159:4
Adair (3) 15:17 103:19 146:17			92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	areas (7) 14:13 133:13 147:16 147:22,24 152:15
Adair's (2) 33:4 112:24			92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	
add (1) 28:25			92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	
addition (2)			92:16 103:16 107:4 107:8,9,17 108:21 109:20 110:15 111:16 112:9,24 113:7 115:18,22 117:22,24 131:11 134:8 137:9,19 139:9 146:20 156:9 164:8,14 165:21 174:10,22 175:24 176:18,19,21 177:2 177:12,15,20 178:2 178:12,13,15 179:13,23,24 180:6 180:16,21	

170:18 arrows (2) 134:14,20 artificial (1) 160:2 asked (37) 14:11 21:12 33:8,9 43:2,6,10,14,20 46:17 47:18,24 49:13,18 50:5,12 56:3 58:3 65:17 82:24 83:14 84:17 87:4,17 88:2 89:15 89:16,25 90:9,18 92:8,15 104:8 165:16 166:20 173:23 179:21 asking (12) 12:18 34:13 48:3,6 71:18 89:19 91:22 143:22 145:24 153:23,24 166:7 aspect (1) 49:25 aspects (4) 52:21 137:16 151:12 176:21 assess (7) 43:21 72:20 107:18 162:12,16 164:16 164:18 assessing (4) 166:17 168:9 170:7 178:22 assessment (16) 11:24 102:9 107:8,17 112:23 134:16 137:13 156:6,11 164:9 165:4 169:11 169:14,16,19 170:2 assistance (1) 143:21 associate (2) 37:21 175:15 associated (13) 15:2,7,12,20 72:22 78:20,24 85:24 136:9 137:5 148:11 153:10 170:7 association (4) 3:17 44:2 151:16 158:17 assume (2) 19:19 55:17 assuming (1) 110:2	assumption (13) 78:3,5,6,12 81:16,23 83:8 84:3 91:13,17 91:19 92:12,16 assumptions (1) 92:2 Atlanta (1) 2:15 atmosphere (1) 113:4 attach (1) 138:22 attached (2) 124:16 185:16 attention (3) 134:23 137:2,3 attitudes (1) 172:14 August (1) 144:5 August/September ... 41:10 automobile (1) 180:7 available (14) 18:24 23:24 26:25 28:21 29:5,22,24 30:6 84:4 88:19 118:2 163:20,23 164:3 average (1) 64:7 avoid (1) 134:23 avoiding (1) 134:24 aware (39) 18:23 42:11,24 45:14 45:17 47:2 56:24 61:9,24 62:5 70:23 71:20,25 76:13 93:5 93:6 94:6,12,19 96:4 99:12 101:6 102:10 106:5 115:16 117:5 127:15 128:19 139:17,25 146:5,7 146:12 159:8 164:11 169:6,25 178:18 180:19 awareness (2) 72:15 95:18 B B (1) 182:8	Bachelor's (1) 51:25 back (26) 28:15 35:2 44:9 51:7 70:3 82:15 92:12 93:7,22 97:25 98:23 100:11 113:18 123:10 132:18 134:17 141:2 145:13 147:13,15 148:21 151:14 152:14 153:7 155:22 177:4 background (5) 11:23 94:14 96:21 98:11 164:23 backtrack (1) 100:15 bad (2) 116:14 145:23 balance (1) 153:10 basal (3) 70:22 85:4,11 based (29) 14:15 15:15 16:21 17:12,23 62:24 64:3 67:20 68:2,4,19,21 74:23 78:17 81:16 82:20 88:12,21 91:13 97:23 103:18 107:25 109:9 112:24 117:15 119:5 138:8,11 154:20 basic (13) 54:22,23 120:4 122:13 156:10 157:21 158:3 172:2 172:22,24 174:12 174:21 179:12 basis (1) 92:2 batch (1) 19:6 Bazargan (2) 29:11 70:18 began (2) 33:25 76:2 beginning (1) 6:16 begins (3) 51:6 100:12 145:13 behalf (8) 3:24 23:7 45:20,24 47:10 61:4,7 107:11	belabor (1) 171:18 belief (1) 185:14 beliefs (1) 172:14 believe (46) 6:11 8:5,14,21 13:13 21:10 22:4,4 24:17 24:23 29:8,14 30:5 30:14 40:9 43:13,17 47:6,11 56:13 58:18 61:5 64:20 67:17 69:8 73:7 74:2 75:6 76:3 77:13 87:7,11 88:2 92:14 97:17 101:24 102:17 106:4 107:2,15 108:4 115:24 116:20 138:2,15 140:13 benefit (4) 132:3,4 153:5 171:20 benefits (1) 153:11 best (2) 67:11 185:13 better (1) 50:20 Bettis (10) 8:7 9:8 29:3 77:9,16 123:25 124:23 141:13 144:7,12 Bettis's (2) 144:13,18 beyond (1) 92:4 big (1) 152:17 bill (6) 24:5,19 26:13,14,16 27:5 billable (2) 38:13,14 billed (5) 24:16 25:21 26:3,5,12 billing (5) 10:25 11:10 23:23 26:10 39:6 Billstein-Miller (1) 3:17 biomedical (2) 52:11,13 bit (9) 21:14 41:2 50:18 90:20 100:15,17	114:10 119:9 171:21 block (4) 71:16,21 114:5 135:9 blockage (4) 15:8,21 86:18,18 blocked (65) 67:14,22 68:10,18 69:6 71:4,5,12 72:4 72:6,7,11,19,23 73:6,14,20,25 74:5 78:2,13,20 81:3,5 81:18,18,19,24 82:3 82:8,18 83:5,11 84:5,7,25 86:16 92:13,17 94:13,13 97:10 102:19 107:20 108:6,23 109:5,22 111:4 112:4,13 113:2,11 114:16 125:16 126:5,11,15 127:9 127:12,16 163:15 165:6 177:13,16 body (6) 124:16 172:18 179:3 179:5,8,9 bolus (1) 70:22 boluses (1) 69:10 bordering (1) 154:17 bottom (8) 75:16 76:8 77:11 93:14 99:20 125:5,7 125:9 Brackin (68) 1:5,6 3:5 8:7 9:5 19:7 29:2 33:23 68:22 69:9,24 70:24 74:7 74:9,23 75:13,17,22 76:2,4,7,11,11,13 78:18 79:6,11,15,20 79:24 81:5 82:6,6 85:3 87:5,13 88:23 89:11,23 90:22 92:10,22 93:9,11,13 93:25 95:19 96:6,17 97:6,13 98:14 99:10 99:10,12,17 102:19 104:17,22 105:12 106:2,6,9,23 128:9 129:21 176:14 178:17 Brackin's (15)
---	--	---	---	---

14:23 15:10 16:16 32:13 34:11 67:22 74:19,21 76:16 79:13 88:17 93:2 95:8 120:9 123:17 Brackin-23 (2) 120:10 123:17 Brackins (17) 17:9 64:8 74:16 104:19 105:9 114:12 115:6 123:21,24 124:18 124:24 141:13 144:8 162:22 163:8 163:12 164:12 brand (1) 155:16 break (8) 5:9,10 9:18 20:16 21:14 50:18,21 100:2 briefly (1) 67:13 bring (7) 6:23 117:3 119:12,24 119:25 120:5 122:10 bringing (1) 122:23 broad (1) 128:3 broadly (1) 174:17 brought (8) 7:2,4,7 10:24 11:7,8 90:5 117:11 Bryan (2) 1:5 3:5 bucket (1) 83:15 build (1) 96:21 bullet (14) 148:3,6 149:5,8,10,13 149:16,19,22,25 150:10,22 151:2 158:16 business (3) 36:2,14 40:19 <hr/> C <hr/> C (1) 2:2 C535.6 (1) 134:22 calculation (1)	109:25 calendar (1) 23:20 call (4) 106:2,7,23 172:17 called (7) 25:4 40:3 86:14 106:18,18 147:8 160:18 calling (3) 106:10 109:4 150:11 CAPA (4) 105:15,18 165:5,10 capacity (1) 1:6 captioned (1) 185:3 capture (1) 137:2 captured (2) 127:20,21 care (10) 16:3,5,18 17:4,13,20 60:13 64:5 108:12 108:13 Carolina (3) 45:2 51:11,21 cart (1) 117:21 case (106) 11:16 14:2 15:17 16:13 18:14,18,20 18:22 19:3,16,25 20:4,8,19 23:13,14 23:17 24:3,14,21,24 25:2,5,7,11,14,23 26:6,21,23 27:4,14 28:17 29:7,13,17 30:12 31:13 34:5 49:3,5,25 50:5,10 54:2,5,16 55:15 56:10 57:15,17,22 58:11,24,24,25 59:16,19,21 61:25 64:17 65:23 66:21 67:4,8,10 72:3,16 73:15 74:17 75:12 78:3,11 80:22 81:2 82:13 88:4 89:22 92:13 99:6 102:21 103:2,11,13,15 107:17 113:13 119:22 123:2 140:3 141:6 145:17,21 146:16 164:16 170:15 175:3	176:17 177:6,11,13 178:7,8,17,17 184:2 case-related (1) 35:9 cases (4) 140:16,20 141:2,9 catastrophic (6) 54:20 79:4 130:22,24 131:8 132:2 categorization (1) 154:18 categorized (1) 53:5 category (1) 122:21 caught (2) 111:18 113:5 causally (1) 102:20 causation (8) 54:5,8 81:15,15,22 83:8 102:22 167:12 cause (8) 82:21 92:21 94:22 95:2 98:2,3 129:7 173:12 caused (3) 14:22 15:9 74:6 causes (2) 82:12 85:2 causing (5) 98:16 126:11 127:11 128:22 135:10 CCR (1) 1:20 CD (11) 9:15,19 11:5,7,13 12:8,16,24 13:3 100:25 182:12 Cedar (4) 1:16 2:4 3:12,21 cell (1) 174:11 center (2) 94:18 149:24 certain (4) 14:13 33:7 154:16,19 certainly (4) 33:20 58:2 113:13 159:4 CERTIFICATE (1) 183:2 certification (4) 157:2,9,12 158:18 certifications (2) 156:24 159:6	certified (4) 123:25 128:11 158:18 158:20 CERTIFY (1) 183:3 cetera (7) 15:15 38:23 39:7 160:4 172:7 173:8 174:16 chair (1) 159:17 chances (1) 113:20 change (8) 69:19 87:21 90:8 92:4 110:8 117:14 143:20 144:20 changed (15) 27:25 56:5 76:12 85:4 91:5 93:9,9,10,16 97:14 99:11 110:5 117:17 152:20 155:15 changeover (1) 114:3 changes (2) 57:24 185:4 changing (5) 91:8 124:4,9,19 132:14 charge (2) 35:10,13 charging (1) 35:7 checked (4) 143:18,22,24,25 checklist (9) 141:12,20,22 142:19 143:8,12,17 182:18 182:20 choose (1) 133:16 circumstances (1) 61:15 citation (1) 123:3 cite (4) 96:7 116:17 119:22 170:9 cited (3) 60:4 121:23 166:8 citing (3) 93:12 119:16 170:5 clarify (3) 121:16 142:15 184:5 clarity (1)	52:5 classification (2) 110:6,6 clean (2) 100:14 135:8 clear (2) 80:6 114:21 cleared (2) 62:6,12 clearly (1) 78:25 client (1) 5:20 Cliff (2) 2:11 3:23 clinical (2) 53:25 120:21 closed (10) 86:17,17,17 91:7,7 94:13,23 97:19 98:16 114:5 closer (1) 151:7 code (3) 108:2,11 109:10 codes (3) 107:25 108:8 184:4 cognitive (3) 44:25 52:2 53:8 collateral (1) 60:9 collect (1) 6:22 come (8) 14:3 28:14 62:21 68:17 69:21 70:21 132:9 176:25 comfortable (1) 173:17 coming (17) 11:15 12:13,23 13:23 34:15,19 67:4,19 74:10,13,16 107:18 108:3 118:3 166:15 169:11,22 commencing (1) 1:18 commercial (1) 122:18 common (2) 54:19 108:22 communicate (1) 137:3 companies (2) 37:13 152:22 company (18)
--	--	--	---	---

35:19 38:19 40:3 42:10,23 43:3,7,11 43:20 44:15 45:8,10 45:19,21 117:4 140:11,17 146:2 compare (1) 20:24 compared (4) 16:17 20:19 110:21 178:21 comparison (1) 161:5 complaints (3) 107:4,18 110:21 complete (4) 28:24 29:4 30:11 185:13 compliance (1) 165:18 complied (9) 49:6,11,17,19 50:10 50:13 115:25 165:12 166:17 comply (2) 116:4 170:6 component (3) 137:11 161:24 176:23 components (3) 55:21 135:19 161:13 comprehensive (1) 61:19 computer (2) 11:8 174:10 con (1) 157:14 concepts (4) 174:2,18 179:23,25 conclude (2) 97:5 103:19 concluded (4) 15:19 98:2,9 181:16 concluding (1) 93:25 conclusion (1) 97:18 conclusions (1) 17:25 conduct (8) 14:6 19:17 24:14 79:9 81:8 107:16 146:19 172:3 conducted (19) 13:25 14:20 15:24 24:17 34:4,9,23 63:4 68:7 113:6 115:20 116:5,9,18	151:18 153:3,23 176:9 177:25 conducting (4) 115:17 116:7 122:16 175:23 confidential (2) 39:15,18 confined (1) 157:18 confirm (2) 56:5 181:8 conform (1) 184:6 confusing (1) 41:2 conjunction (3) 61:10 69:7 134:19 connect (1) 82:4 connected (5) 78:23 94:25 96:25 99:15 125:23 connecting (2) 98:7 124:13 connection (1) 147:2 connector (9) 15:4,8,14,22 16:8 99:15 135:8,10,13 consequence (1) 111:13 consequences (3) 130:5 131:8 134:24 consider (6) 48:11 52:15,18,22 84:24 85:3 consideration (2) 121:12 146:23 considered (1) 133:4 consistent (16) 54:21 68:21 74:25 82:22 88:14 91:8 92:24 94:16,17,19 94:22 98:15,17 123:8 134:15,22 consulting (24) 35:21 36:2,6,9,12,15 36:16,18,19,24 37:6 37:8,10,12,14,17 38:3 39:11 41:14 42:8,14,22 45:13 140:9 consumer (3) 64:7 122:18 174:15 consumers (2)	152:23 153:9 contacted (4) 23:13,16 25:6,9 contacts (1) 152:14 contain (1) 170:14 contained (4) 59:22 170:12,13 183:5 containers (3) 154:7,9,10 contains (1) 7:4 contaminate (2) 98:6 125:19 contaminated (1) 92:19 contaminates (1) 96:22 contaminating (3) 85:24 96:24 127:2 context (5) 47:17 48:24,25 58:20 61:21 continuing (2) 155:23 156:2 contractor (2) 40:2 41:12 contribute (1) 79:4 contributed (2) 14:22 15:10 controls (2) 52:24 53:14 convenient (3) 118:19 119:10 122:22 conversations (2) 68:5,20 conveyed (1) 106:6 cooperation (1) 151:16 copied (1) 104:15 copies (1) 142:20 copy (19) 5:25 6:7 7:7 8:17 9:15 9:16 10:6,12 11:6,7 11:8,10 21:10,11 22:24 28:6 123:13 123:20 142:6 Corporation (5) 40:19 41:6,15 53:4 122:17	correct (77) 4:19 21:17 25:24 26:6 26:8 37:20 39:25 42:21 45:8,21 51:12 51:13,23 52:3,4 53:22 54:2,3,6,13 55:2 56:19 57:12,13 58:5,18 59:19,23,24 60:3,4 63:11,20 64:19,24 65:9,15,19 65:24 67:8 70:18 75:9 76:23 77:6 81:3,25 82:2,14 83:13,25 84:16 85:12 87:6,23 91:14 91:15 92:13 95:13 96:13 100:20 102:2 102:23 103:2,23 123:6,19 131:13 132:25 137:21 149:19,25 167:6 178:4,24 183:9 184:7 185:12 corrections (3) 185:4,15,16 correctly (5) 88:25 91:11 109:2 128:13 135:24 counsel (3) 2:7,16 3:18 couple (5) 10:4 46:13 87:3 147:6 171:12 course (5) 79:3 109:18 110:8 157:21,22 courses (4) 157:25 158:3,6,12 court (7) 1:2 3:7,16 4:3 139:14 181:7,11 cover (2) 28:15 65:3 covered (3) 83:22 141:13 156:10 coworkers (3) 118:20 119:10 121:5 crane (1) 157:6 create (4) 79:4 153:21 155:18 155:21 created (3) 14:17 54:18 56:22 critical (1) 145:17	criticisms (7) 127:23 129:13 130:7 138:7 145:20 146:14 147:4 CRR (1) 1:20 current (6) 10:23 31:25 35:8,19 95:15 159:17 Curriculum (2) 10:12 182:13 Curtis (10) 93:21,24 95:11,17 96:4,15 97:8,18 98:18 128:18 Curtis's (5) 32:22 96:7,20 97:4 98:24 cut (2) 13:16 49:23 CV (15) 10:6,7,9,22,23 12:14 28:14 35:2,18,22 147:7,7,12 155:22 160:7 <hr/> D <hr/> D (1) 182:2 D-F-M-E-A (5) 177:12,17,20 178:6 178:14 d/b/a (1) 36:3 daily (2) 69:15,16 Dan (2) 2:20 3:14 data (4) 72:17 107:23 110:10 127:19 date (7) 1:19 7:15 10:9 23:9 26:11 87:22 185:7 dated (5) 10:20 29:20 144:4,5 183:10 dates (1) 57:21 daughter (1) 129:22 day (8) 24:6,11 71:8 106:12 106:12,13 144:7 185:23 days (1)
--	--	--	--	--

130:16 deal (7) 160:10,12,14,15 167:5,15 168:19 dealing (1) 155:7 dear (3) 108:12 164:12,18 death (5) 14:23 15:10 111:11 135:13 136:23 decades (1) 123:10 Deceased (1) 1:7 decisions (3) 172:10,15 173:12 defect (2) 82:5,9 defective (6) 65:8,12,21 80:8,14 81:11 defects (1) 173:25 defendant (2) 41:21 42:7 Defendants (3) 1:10 2:16 3:24 deficient (1) 16:19 degree (4) 52:6,8,11,14 delayed (1) 132:10 delegating (1) 133:10 delivered (4) 69:13,17 71:6,8 delivery (4) 15:20 72:10,22 135:11 demonstrate (4) 88:6,13 89:6 97:12 demonstrated (3) 74:24 88:24 143:19 demonstrates (1) 97:9 demonstrating (1) 77:22 Dennert (26) 11:21,21 18:10,14 19:11,12,25 20:9 21:5 46:5,10,14 57:15,17,21 58:11 58:24 78:19 102:25 103:11,15 104:7,16	176:14 178:7,17 depending (3) 36:20 110:15 137:24 depends (3) 52:17,20 113:13 DEPONENT (1) 185:9 deposed (3) 4:22 141:4,5 deposition (89) 1:14 3:4,11 4:18,22 5:5,14,19,24 6:11 6:13,24 8:6,13,15 9:5,6,8,9,12 10:4 12:7 17:12 21:13,16 21:20 22:3,6,10,17 27:17,20 29:2,3,3 29:10,11,12,20 30:3 31:22 32:2,4,8,13 32:16,19,22,25 33:4 35:12,17 56:6 74:19 74:21,24 75:6 77:8 87:10 88:3,15,17,22 89:5 93:22 95:22,23 103:12,22,25 104:5 106:25 109:12 120:9 123:17 124:22 144:12,23 158:11 162:3,7 170:20 172:20 181:5,15 182:11 183:7 185:3,12 depositions (12) 7:25 8:4,10,19 9:4 27:15,24 28:25 31:12,23 33:22 57:25 Describe (1) 153:25 description (2) 173:21 182:9 design (72) 11:24,24 16:3,4 17:4 17:20 45:16 47:8,13 48:5,17 52:19,23 53:12 54:16,17,21 54:22 55:5,8,16,21 56:8,11,18,22 78:21 80:8,14 83:20,21 85:15,18,20 86:4,21 111:14 112:17,21 115:15 117:23 128:8 129:15,17 131:9,12 132:24 133:16,21,23 134:4 136:12 146:20	149:21,24 156:23 161:7 165:14 167:19,23,24 168:10 172:25 173:8,15,15,18,25 174:2,23 176:22 179:9 design-based (1) 53:3 designed (12) 17:17 54:25 83:24 86:9 93:6 112:15 115:21 122:17 130:10 133:12 136:25 146:22 designers (5) 16:6 173:5,5,6,6 designing (4) 16:6 64:5 146:18,22 designs (8) 55:12 83:23 84:4,9,11 84:13,14 133:7 determinations (1) 64:12 determine (12) 33:11 49:18 68:9 72:21 82:17 83:4,10 83:14 85:14 97:5 117:13 137:14 determined (3) 93:23 97:22 108:13 determining (2) 73:5 74:4 developed (5) 17:22 115:21 118:5 122:4 139:3 developing (3) 16:7,15 122:8 development (17) 16:3,4 17:4,18,21 48:5,18 86:4 111:25 112:10,14 113:5 149:22 167:20,23 167:24 168:4 device (71) 37:13 42:10,23 43:3,7 43:8,11,16,19 44:5 44:15 45:8,10,13,16 45:19,20,22,24 46:8 46:16,18,20,22,25 47:5,25 48:18 50:10 55:2 56:8,9,12,15 56:15,19,23 57:2 58:16 60:12 61:4,15 61:17,20 105:23 107:5,10,13 120:17	120:25 161:13,14 161:20,22,24 162:2 163:21 164:2 167:9 169:11 174:14 175:24 176:13 178:2,15,19,21 179:2 180:7,17,21 devices (37) 13:6 16:4 42:15,16,20 44:16 57:5 59:5,12 60:22 62:11,16 150:6,8 156:3,14,17 156:19,23 159:7 160:11,13,25 161:3 161:7,8,17 166:6 167:5,16,18 168:24 169:4 174:3,7 179:6 179:7 Dickerson (2) 2:20 3:14 different (28) 12:19 14:11 37:3 70:25 90:20 107:24 107:25 108:3 110:15 126:13 132:7 137:15 141:6 146:7,11 147:16,21 153:21,22 156:10 156:12,12 157:25 158:6 166:10 172:21 174:9 176:21 differently (2) 83:25 142:22 differing (1) 137:24 difficult (2) 112:3,12 direct (1) 152:9 directing (1) 125:8 directions (1) 155:13 directly (1) 152:23 disagree (2) 112:2,11 disc (7) 7:4,6,8,17,18,22 30:20 disclosed (2) 23:6,10 disclosing (1) 22:22 discovered (2)	139:5 165:7 discovery (4) 15:16 16:12 94:16 109:12 discussed (6) 55:21 59:7 77:9 80:23 83:17 170:19 discussing (1) 109:3 dispense (1) 5:3 displays (2) 52:24 53:14 dissertation (1) 155:7 distinction (1) 35:23 distraction (1) 130:18 District (4) 1:2,3 3:7,8 Division (2) 1:3 3:9 docket (1) 3:9 doctor (1) 51:17 doctoral (2) 155:6,7 document (7) 6:10,12,16 118:13 122:12 165:3 167:7 documents (14) 5:18 7:22,24 8:4,10 8:18 12:3,12 22:9 27:19 78:18 79:2 109:12 142:10 doing (14) 36:2 38:2 41:13 43:25 61:23 91:11 114:2 117:20 127:14 128:20 151:5 153:16 154:11 169:7 dominant (1) 137:19 dose (1) 69:16 dosing (1) 69:15 Dr (6) 4:13 10:13 30:4 51:10 171:17 179:21 draft (3) 43:21 181:9,12 drafting (2)
---	---	---	--	---

8:22 74:20 draw (2) 134:23 137:2 drip (1) 98:6 drive (4) 7:11,21 8:13 9:19 drives (1) 9:21 driving (2) 148:4,16 drops (1) 129:4 drug (7) 43:25 44:23 151:15 154:3,12,24 155:3 drug-related (2) 44:8 45:4 drugs (5) 44:19,20 155:9,10 179:8 dry (1) 135:9 Duarte (1) 32:17 Duarte's (1) 32:16 due (2) 78:21 84:7 duly (1) 4:7 DVD (8) 3:3 50:25 51:7 100:5 100:12 145:6,13 181:3	easier (1) 115:8 easy (1) 173:16 education (8) 11:22 64:4 116:23 119:6,19 155:23 156:2 169:24 effect (5) 125:24 151:25 152:2 176:19 179:22 effective (1) 66:5 effectiveness (1) 62:16 effects (8) 155:14 175:23 176:20 178:11 179:24 180:6,16,21 efficacy (6) 62:23 63:3,10,19 64:11,18 eight (3) 121:11 125:2 129:20 either (12) 26:12 32:11 33:21 43:20 58:24 77:22 106:12 113:25 126:8,9 143:15 171:5 electrical (1) 173:7 eliminate (3) 84:5 86:5 127:4 eliminated (1) 86:10 eliminates (1) 126:25 eliminating (1) 129:15 email (1) 22:20 emails (2) 94:18 109:2 emergency (1) 157:15 emphasize (4) 124:23 129:21 134:14 164:25 emphasized (3) 75:25 129:25 134:11 emphasizes (1) 130:3 employed (1) 41:10 employee (5)	95:12,14,16 145:20 146:15 employees (4) 94:12 118:20 145:17 147:4 employment (1) 38:22 endeavored (1) 6:22 ended (1) 41:16 endocrinologist (1) 53:20 ends (5) 50:25 100:5 145:6 181:3,5 energy (1) 30:23 engineer (3) 53:5,11 85:16 engineering (12) 13:5 52:8,11,14,16,19 52:21 53:8,9,16 159:20,23 engineers (4) 159:11 173:4,7,7 ensure (4) 19:24 20:13 135:7 153:9 ensuring (1) 163:17 entire (4) 61:17 118:12 137:14 177:17 entirely (1) 138:7 entities (1) 41:19 entry (2) 26:14 157:19 environment (1) 120:21 environments (2) 120:23 146:24 EO (1) 108:11 equalization (1) 113:3 equipment (1) 174:15 ergonomics (13) 44:25 51:15,22 53:2,7 53:17 147:9,17,22 148:15 150:4 159:14 172:18 error (9)	106:11,15,20 107:25 108:2,8 109:10 110:6 176:22 errors (3) 177:3,4 184:7 ESQUIRE (2) 2:3,11 essentially (6) 14:10 41:12 80:9 130:9 158:4 173:18 estimate (6) 27:3 39:13,14,16 108:9 140:19 et (10) 1:9 3:5,6 15:15 38:23 39:7 160:4 172:7 173:7 174:16 evaluate (4) 43:11,15 47:19,24 evaluated (2) 82:11 116:11 evaluating (2) 83:16 137:20 evaluation (4) 115:18,23 118:18 122:14 evaluations (1) 102:8 evening (11) 69:11 75:13 76:22 81:6 91:6 92:21,25 93:10,16 97:6 98:14 event (17) 16:16 72:7,7,23 74:6 81:19 82:8,18 91:8 91:18 95:7 106:13 109:5 110:7 114:8 127:12 177:16 events (11) 68:6 82:24 94:14 108:6,9,15,19 109:9 109:22 110:3,20 eventually (1) 94:11 evidence (9) 68:15 71:24 76:21 85:7 91:11,20 93:8 94:21 183:4 evident (1) 82:5 exact (4) 66:8 92:14 110:23,25 exactly (6) 18:11 30:16 42:5 128:23 144:2 157:24	examined (2) 4:8 19:4 example (19) 43:4 52:10 55:13 66:19 85:4 93:21 107:21 119:18 122:7 128:18 146:17 155:6,12 156:6 161:5 167:10 172:4 173:3 176:20 examples (1) 134:19 excluded (2) 139:14,20 exclusively (1) 160:22 excuse (9) 44:7 53:7 61:11 84:6 86:18 90:15 91:9 112:8 150:16 exemplar (2) 19:2,4 exhaustive (1) 63:21 exhibit (42) 5:23 6:3,10 9:15,23 10:11,12,15 12:8,16 12:25 22:20 23:2 28:6,9 35:3 69:24 70:4,6,24 120:8,12 123:14 141:19,21 141:24,25 142:9,18 143:6,7,9,11,16 182:10,12,13,14,15 182:16,17,19 exhibits (5) 9:17 27:18 70:14 106:24 107:23 exist (2) 86:24 131:20 existence (1) 122:10 existing (2) 155:14,20 exists (1) 79:5 expect (1) 130:25 experience (21) 11:20 14:15 20:9 64:4 116:24 117:6 119:6 119:20 147:9,21 148:14,20 150:5,10 158:14 169:24 175:11,18,23 176:7 178:6
E E (9) 2:2,2 4:10 171:14 175:8 179:17 180:12 182:2,8 E2 (2) 16:12,20 E3 (1) 17:2 E4 (2) 17:18 133:15 EA30 (1) 108:11 earlier (9) 21:12 27:17 70:16 72:25 82:19 87:4 100:17 119:10 172:20 early (2) 16:16 119:11				

experienced (1) 128:20	113:7 115:13,17,22 116:2 117:22	50:11,13 57:3,4,10 58:10,15 60:17,20	filled (1) 78:23	folks (2) 44:3 117:4
experiences (2) 19:24 172:13	118:17 119:15 120:16 121:11,13	62:2,7,12 63:6,12 63:15,20,22 64:10	filling (1) 124:12	follow (12) 87:3 113:15,19 114:7
experimentation (5) 14:2,5 19:17,21 68:8	121:24 122:13 123:5,9 134:8 138:8	66:3,8,9,15,19,22 67:7 100:18 101:4,9	final (4) 116:11 154:3 181:9	114:10,13 115:12
expert (36) 7:12 8:2 10:7 12:24	147:8,17,22 148:9 148:11,14,19 150:4	101:19,22 102:3,5 115:12 116:2 118:8	181:12	121:19 127:3,6,13
18:4 22:23 23:7	150:14 151:19 156:8,11 159:13	120:16 121:23 123:5 151:16 152:5	finally (1) 117:14	144:2
25:15,18,23 26:5	165:22 166:5,18 168:2,9,19,23	152:14 153:7 165:13,18,21,23	find (3) 33:14 70:3 82:25	follow-up (1) 10:4
28:2,7 36:25 37:9	171:22,24 172:2,22 173:2,22 174:2,12	166:5 167:4,8 168:15	finding (1) 98:19	followed (8) 90:6 113:10 115:6
38:8 48:12,14,17,20	174:21 175:2,12 178:23 179:11	FDA's (3) 13:4 62:15,24	findings (2) 152:9 154:21	126:16 127:16
48:24 52:16,19,22	factors-type (1) 152:16	feasibility (2) 84:9,14	fine (5) 50:19,22 64:15	135:21 136:5,15
59:23 67:7,10 85:18	facts (1) 184:6	feasible (1) 86:8	141:18 142:14	following (6) 7:25 27:12 69:18
102:24,25 103:14	failed (5) 79:14 81:8,9 115:12	feature (1) 86:22	finished (1) 144:15	90:10,23 139:5
104:16 132:22,25	146:19	features (1) 152:3	fire (1) 157:14	follows (4) 4:8 125:13 126:2
140:20 182:15	failing (1) 130:6	February (1) 10:20	firearm (1) 159:2	128:10
expertise (4) 52:23 53:16 147:16	failure (16) 14:22 15:5 16:24 79:9	fed (2) 153:7 177:4	first (16) 4:7,17 14:19 15:11,25	font (2) 151:25 154:16
148:8	79:18 82:4 106:11	Federation (1) 157:6	23:12 24:2 25:6	foregoing (1) 185:11
experts (4) 39:5 50:3 55:15,18	175:23 176:19,20	feed (1) 178:11	35:6 57:13 86:9	foreign (1) 94:24
explain (3) 26:2 41:3 78:16	178:11 179:22,24	feel (1) 170:2	93:3 128:10 129:5	forensic (23) 35:23,25 36:13,15
extent (1) 175:18	180:5,16,20	fellow (1) 118:20	130:12 161:15	37:2,11,17,25 38:4
extrapolate (1) 117:8	failures (4) 79:12,22 81:12 82:9	fictitious (1) 155:19	first-time (3) 117:7,8 118:10	38:6 39:24 40:6,11
extremely (1) 108:22	fair (3) 63:8 92:15 153:9	field (6) 52:25 53:6 159:25	Fisk's (1) 32:19	41:7,14,17 42:3,8
	fairly (2) 78:25 120:3	171:21,23 173:22	five (8) 38:20 90:7,9 128:10	46:9 61:11,12 140:8
F	fall (1) 122:20	figure (3) 39:17 91:24 128:21	141:7 144:24	147:14
F-M-E-A (4) 176:13,16 177:7,12	falls (1) 148:18	figures (1) 108:3	168:13,18	foresaw (1) 152:15
face (1) 80:15	familiar (9) 34:24 56:7,14 57:3	file (10) 5:20 8:16 24:9 29:19	fix (1) 143:2	foreseeable (3) 15:13 111:13 136:10
fact (18) 15:19 16:18 54:17	59:10 61:24 92:9	56:8,12,18,22 85:8	fixed (2) 54:21 128:7	15:13 111:13 136:10
62:10 69:7 76:6	169:13,15	125:6	flexibility (1) 172:19	foreseeably (1) 80:16
78:13 81:17 92:21	family (1) 74:15	files (1) 33:13	flip (3) 125:4,6 134:14	forget (1) 173:13
93:8,23 95:9 97:12	far (1) 57:23	fill (10) 68:24 69:3,18 75:6	flipping (1) 138:20	forgot (1) 35:3
116:10 129:2,23	fatigue (1) 130:18	111:5 128:22	FMEA (3) 176:8,10 177:5	forklift (2) 157:9,13
132:8 137:3	FDA (69) 13:12 42:12,13,15,19	143:20	focus (4) 31:12 33:8,10 165:19	form (1) 101:23
factor-type (1) 174:9	43:15 47:8,12,18		focused (3) 44:22 53:2 177:15	formal (1) 61:2
factored (1) 74:2	48:2,4,11,17,24		focuses (1) 54:11	formatted (1) 137:2
factors (78) 11:23 13:5,11 14:21	49:6,11,17,19,25			formatting (2) 152:2 154:17
15:25 38:25 39:5				formed (1) 49:10
53:2,5,17 54:12,24				former (1) 95:12
57:2,11 58:10 64:2				
79:10 80:24 81:9				
83:17 85:17 100:19				
102:8 103:16				
111:16 112:9,17,20				

forms (1) 118:17 forth (4) 39:4 130:6 147:2 172:16 found (6) 16:18 66:3 93:11 98:18,21,23 Foundation (2) 157:21 158:3 four (10) 35:4 141:7 145:14 167:4,14 168:8,15 168:17,25 181:4 frame (6) 111:22 134:17 150:13 150:24 151:4 153:18 front (4) 26:10,24 112:21 147:7 full (1) 177:20 fully (1) 183:5 functionality (1) 34:10 further (3) 171:9 179:14 180:23 future (1) 128:14	17:8 19:22 20:12,23 20:25 21:4,6 60:14 75:2,11 90:6,10,24 94:23 96:23 104:24 105:4,9,14 113:9,21 113:25 115:7 120:8 123:14,15,20 125:3 125:14 126:3 127:7 127:18,22 128:4 129:19 130:2,8,13 132:13 134:10 135:19 136:4,14 137:6,12,14 153:9 182:16 Gharabli (1) 32:25 give (6) 142:20,24 147:15 166:13 171:20 176:6 given (11) 31:11 49:12 58:13 72:14 79:12,16 85:23 87:22 90:5 101:8 112:15 giving (2) 121:22 152:22 global (2) 94:18 98:22 go (14) 5:23 10:10 48:8 66:14 70:3 72:14 80:4,6 113:18 137:22 141:4,5 147:19 154:14 goal (1) 173:15 goes (1) 128:11 Goidel (2) 9:11 162:25 going (57) 5:22 7:21 9:14 21:24 22:19 28:5 30:21,23 47:15,21 49:15 50:15,24 54:4,7,15 55:4 60:18 64:6 67:13 77:17 81:6,20 84:21 85:9 91:24 93:23 98:12,13 99:3 99:24 100:4,14 115:4 116:24,25 117:10,14 118:17 119:25,25 120:7 122:9 123:9,11 124:14 131:7	138:13,13,21 139:9 141:15,19 145:6 148:21 171:19 181:6 good (9) 3:20 4:13,15,15 39:14 57:19 116:8,13 146:2 Gosmanov (1) 30:4 govern (1) 56:18 government (1) 152:20 graduate (2) 43:24 148:22 grants (1) 151:15 graphic (1) 173:5 great (4) 30:22 33:15,16,16 green (2) 129:3,4 GREENBERG (1) 2:12 group (3) 38:25 39:2 159:18 guarantee (1) 128:13 guard (14) 75:8,24 77:24 86:6 89:8 90:14,16 94:4 97:3 98:5 113:23 126:20 128:25 130:21 guarding (1) 136:12 guess (4) 7:21 40:17 150:12 151:6 guidance (16) 13:10,22 31:11 57:14 58:9 59:4 100:18 116:2,17 118:9 119:16 121:24 123:5 167:4,7 168:25 guidances (19) 12:3,7,12,22 57:2,4 57:10,11 58:15,22 59:7 101:4,25 115:12 119:21 166:3,5 168:23 169:4 guide (52)	17:8 20:12,12,23,23 21:5,7 60:15 75:3 75:11 90:6,10,24 104:24 105:2,4,10 105:14 113:10 115:8 120:8 123:8 123:12,15,16,21 125:3,15 126:3 127:8,18,23 128:4 128:10 129:19 130:2,8,13,14 134:10 135:20 136:4,14,22 137:6,7 137:12,14,24 138:4 153:15 182:16 guidelines (5) 17:24 54:23,24 116:21 168:3 guides (4) 19:22,22 20:25,25 guy (1) 146:21 guys (3) 5:18 91:24 144:24	128:8 happy (2) 135:3 159:4 hard (1) 11:6 Hartley (1) 8:22 Haverty (47) 2:3 3:20,21 5:20 6:9 14:12 21:17,19,23 22:3,21 23:18 24:12 24:20 25:4,10 26:17 55:23 63:2,12 64:9 66:6 68:5,20 70:8 80:5 85:22 91:21 95:20 96:10 97:15 101:11 104:8 114:17,22 142:7 146:3 166:20 171:11,16 175:5 179:14,19 180:10 180:25 181:10 182:6 Haverty's (1) 31:16 hazard (24) 15:2,7,12,19 78:24 80:15,22 84:15 86:11,24 111:23 112:5,13 128:7 131:19 133:3,16,25 134:23 136:9 139:10 146:20 170:7 178:12 hazards (8) 47:25 83:16 133:11 137:15 139:4 176:24 177:3,21 head (1) 11:19 header (1) 135:6 health (2) 108:12,13 hearing (1) 172:6 held (3) 1:15 3:11 42:4 help (2) 94:18 153:7 helped (1) 45:5 helpful (2) 65:2 83:3 helpline (3) 106:2,7,19
<hr/> G <hr/>			<hr/> H <hr/>	
GA (1) 2:15 gait (2) 148:23 172:20 Gary (2) 1:5 3:5 gather (2) 172:5 173:11 gathering (1) 151:25 general (6) 11:22 154:24 169:16 169:24 173:21 179:25 generally (9) 5:21 56:11,15 136:19 151:17 152:11 153:3 168:10,20 germane (2) 62:25 162:7 Germany (1) 97:25 getting (48)			H (1) 182:8 Haddonfield (1) 2:6 half (1) 21:25 hallway (3) 118:18 119:11 122:21 hand (7) 5:24 9:16 10:19 22:20 137:19 138:8 142:5 handed (1) 123:13 handful (2) 108:5 175:21 handle (1) 20:7 handled (9) 18:6,8,9,14,17,21 19:2,13,19 handling (2) 18:13 126:19 hands (1) 126:22 happen (1) 112:25 happened (7) 80:12 95:6 96:5,8,16 97:6 139:24 happens (1)	

hereon (1) 185:15	116:2 117:22 118:17 119:15	19:23 20:12 114:7 115:20 117:13	including (5) 17:7 38:22 75:3 88:7 88:25	115:14,16 124:5,9 124:14,15,20
herewith (1) 185:17	120:16 121:11,13 121:24 122:13	128:4 130:14 134:16 138:20	income (2) 39:10,21	125:24 133:18 135:14 138:23
hierarchy (1) 54:22	123:5,9 134:7 138:8 147:8,17,22 148:9	Illuminating (2) 159:20,23	incorrectly (1) 75:14	143:19,20 144:20 162:22 163:4,10 165:15
high (1) 27:7	148:10,14,19,23 150:4 152:16 156:7	imagine (3) 31:7,14 135:23	independent (7) 40:2 41:11 63:5,5 69:10 79:20 80:11	ingredients (1) 155:13
higher (3) 140:25 141:8,10	156:8,11 159:13 165:22 166:5,18	immediate (1) 181:12	indicate (2) 89:22 103:15	initial (2) 103:10,14
highlight (1) 138:19	168:2,9,19,23 171:22,24 172:2,20	impact (6) 62:13,17 73:4,13,19 73:24	individually (1) 1:5	initially (3) 8:15 23:16 28:3
highlighted (1) 124:19	172:22 173:2,19,19 173:22 174:2,9,12	imperfect (1) 129:14	industrial (1) 173:6	initiate (1) 66:12
highlighting (1) 21:9	174:21 175:2,12 178:22 179:3,5,7,9 179:11	implanted (2) 179:3,7	industries (1) 146:11	initiated (1) 111:5
Highway (1) 2:5	humans (1) 174:8	implement (1) 115:21	industry (7) 60:14 86:13 165:20 166:18 167:8 168:23 169:9	injuries (1) 79:4
hiring (1) 39:4	hundred (4) 131:2,3,4,5	implemented (1) 133:22	infers (1) 122:23	injury (11) 14:23 15:10 54:20 82:5,6,10 111:11 130:22,24 135:13 136:22
historically (2) 41:22,25	hurrying (1) 130:18	important (3) 33:18 121:12 158:10	information (43) 15:15,16,18 17:6 18:2 26:10 27:23 44:2 60:7 71:14 94:15 95:5 104:6 105:13 106:6,8,14,22 137:4 151:15,23,24,25 153:5 154:18,19 155:9,12,19 162:13 162:17 163:7 164:23 171:4 172:5 172:9,10,11,23 173:6,11,14 177:2	input (1) 112:17
history (7) 56:8,11,15,18,22 69:15 108:17	hypothesis (1) 15:4	impossible (2) 97:20 131:3	inform (2) 163:2 165:2	inputting (1) 176:10
hold (6) 48:14,16,19,21,23 170:20	hypothetically (1) 136:13	improper (6) 15:9 116:12 118:7 131:24 132:5 146:21	infuse (1) 179:8	inquire (1) 152:15
holding (2) 67:6,9	I	improperly (2) 116:5,15	infusing (1) 179:5	inquiry (2) 25:2,3
home (3) 90:5 158:21,22	IBM (13) 40:25 41:5,7,11,13,15 53:4 122:16 160:21 160:23 173:4 176:7 178:10	improve (1) 153:8	infusion (62) 15:2,14 16:9 18:22 19:5,13,18 20:5,7 20:13,18 34:5,12 55:6 62:6 66:4,12 66:23 67:23 68:8,9 68:13 69:19 76:12 78:21 79:7,7,16,23 87:15,21 90:8 91:6 93:10,16 97:14 99:11 104:20 110:11,14,17,22 113:17 114:3	inserting (1) 124:15
Hopefully (1) 142:22	idea (3) 40:16 95:21 96:16	improving (1) 156:8	informed (2) 163:2 165:2	inside (1) 113:3
horse (1) 117:22	identification (7) 6:4 9:24 10:16 23:3 28:10 120:13 142:2	in-depth (1) 108:24	infuse (1) 179:8	inspected (2) 68:12 185:2
hour (9) 21:25 24:7 31:9 35:8 35:11,13,17 50:15 145:4	identified (8) 60:21 84:15 86:3 111:8,23,24 112:10 152:17	inadequate (1) 80:14	infusing (1) 179:5	instance (1) 136:3
hourly (2) 35:6,8	identify (4) 112:4,12 134:8 139:10	inappropriate (1) 85:20	infusing (1) 179:5	instances (1) 136:19
hours (9) 22:15 25:21,24 26:6 27:7,9 31:6 144:8 171:19	identifying (2) 33:23 108:5	incident (10) 61:12 68:23 78:18,19 87:9,14 88:5,24 111:4,10	infusing (1) 179:5	instruct (1) 125:3
human (87) 11:23 13:5,11 14:20 15:25 38:25 39:5 53:2,5,17 54:12,23 57:2,11 58:9 64:2 79:10 80:24 81:8 83:17 85:17 100:18 102:8 103:16 111:16 112:9,16,20 113:6 115:13,17,22	IFU (15) 20:18 75:10 104:20 112:19 113:14,16 113:20 115:25 116:11 117:14,19 117:21 118:4 138:17,23	incidents (1) 127:15	infusing (1) 179:5	instruction (3) 131:6 136:5 163:12
	IFUs (9)	include (5) 29:21 30:17,19 86:21 161:21	infusing (1) 179:5	instructional (1) 17:5
		included (8) 13:3,8 18:4 27:18 29:19,23 112:23 137:11	infusing (1) 179:5	instructions (49) 11:25 14:24 15:6 16:25 17:16,21,23 43:4,12,16,22 44:7 53:14 54:12 55:20 58:17 59:6 60:8 62:22 75:2 79:19 80:23 81:10 83:18
		includes (3) 118:15 119:20 173:19		

94:9 113:9,16 114:11,14,18,24 124:9 125:13 126:2 127:3,7,13,17,24 128:6 133:18 135:20 136:14 137:20,24 140:3,12 162:20 163:9 instructor (1) 158:17 insulin (104) 15:21 18:7,9,9,13,15 19:13,18 20:4,24 34:4,10,11 46:6 61:25 64:18,23 65:6 69:12,13,22 70:13 71:5,6,8,13,15,17 71:21 72:2,4,9,10 72:18,22 74:7 75:9 75:15,23 76:3,8 77:5,11,18,20 78:24 79:3 82:13,22 84:6 85:2 86:13 88:8 89:2,9 90:7,13,14 90:17 92:20,23 93:15 94:4,9 97:3 98:4,6,17 99:19 105:2,10 113:21 114:4,12 124:5,20 125:9,15,20,21 126:4,5,11,16,18,21 126:21,25 127:11 128:16,16,25 129:24 130:20 134:12 135:22 136:2,7,16 137:10 163:3,9,18 165:14 insulinization (1) 135:12 integrated (1) 113:6 integrating (1) 112:20 intended (3) 118:23 121:15 129:10 intending (1) 132:16 intent (2) 31:16 125:11 intention (1) 130:17 interact (3) 20:6 118:4 174:8 interacting (1) 44:4 interaction (3)	52:25 120:25 179:12 interest (2) 151:22 158:13 interface (1) 53:13 International (2) 40:19 157:5 introduce (2) 3:18 131:24 introduced (5) 86:23 131:16,18,19 132:13 introducing (2) 64:5 131:18 inversion (2) 134:11 138:19 invert (1) 130:19 investigate (1) 85:6 investigated (1) 148:10 investigation (16) 11:20 14:17 18:10 19:10 20:8 36:13 61:11,12 63:5,22 66:14 72:13 85:14 94:2 108:24 165:5 investigations (2) 40:6 92:3 invoices (1) 10:25 involve (1) 79:11 involved (21) 18:14 31:20 36:21 44:4,14 45:8,10,15 45:18 46:23 47:3 56:10 68:13 105:15 105:18,21 107:3,7 150:13 159:25 179:10 involvement (2) 58:11 173:25 involves (1) 171:22 involving (1) 61:13 IPAF (1) 156:25 irrespective (1) 80:25 ISO (10) 59:10 169:9,13,15,18 169:25 170:5,9 180:15,19	issuance (3) 7:25 27:12,24 issue (24) 18:18,19,22 19:3 34:11 50:10 55:6 61:25 67:15 74:5 80:6 87:14 104:4 119:3 128:3 137:4 163:13,13 164:20 164:24 165:6 170:8 177:7,18 issued (6) 7:16 13:12 57:3 58:10 140:11,22 issues (14) 16:24 31:20 54:13,14 55:12 61:16,18 80:24 83:17,18 148:9,15 165:22,24 itemized (1) 6:19 items (1) 143:17 <hr/> J <hr/> J (190) 1:1,14 2:1 3:1 4:1,6 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 21:1 22:1 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 36:1 37:1 38:1 39:1 40:1 41:1 42:1 43:1 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1 52:1 53:1 54:1 55:1 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1 71:1 72:1 73:1 74:1 75:1 76:1 77:1 78:1 79:1 80:1 81:1 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1 96:1 97:1 98:1 99:1 100:1 101:1 102:1 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1	116:1 117:1 118:1 119:1 120:1 121:1 122:1 123:1 124:1 125:1 126:1 127:1 128:1 129:1 130:1 131:1 132:1 133:1 134:1 135:1 136:1 137:1 138:1 139:1 140:1 141:1 142:1 143:1 144:1 145:1 146:1 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1 162:1 163:1 164:1 165:1 166:1 167:1 168:1 169:1 170:1 171:1 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1 180:1 181:1 182:1,4 183:1,7 184:1 185:1,19 Jane (1) 8:22 January (24) 69:13,17,18,21 74:8 75:14,20 76:19,22 77:4 78:14 81:6,20 81:20 91:6 92:22 93:17 95:8 96:5,17 97:7,13 98:15 99:8 Jennifer (3) 1:19 3:16 183:14 Job (1) 1:23 jog (1) 34:22 John (1) 32:17 join (1) 41:7 joined (2) 41:16 147:14 JR (190) 1:1,15 2:1 3:1 4:1,6 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 21:1 22:1 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 36:1 37:1 38:1 39:1 40:1 41:1	42:1 43:1 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1 52:1 53:1 54:1 55:1 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1 71:1 72:1 73:1 74:1 75:1 76:1 77:1 78:1 79:1 80:1 81:1 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1 96:1 97:1 98:1 99:1 100:1 101:1 102:1 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1 116:1 117:1 118:1 119:1 120:1 121:1 122:1 123:1 124:1 125:1 126:1 127:1 128:1 129:1 130:1 131:1 132:1 133:1 134:1 135:1 136:1 137:1 138:1 139:1 140:1 141:1 142:1 143:1 144:1 145:1 146:1 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1 162:1 163:1 164:1 165:1 166:1 167:1 168:1 169:1 170:1 171:1 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1 180:1 181:1 182:1,4 183:1,7 184:1 185:1,19 Judge (1) 139:21 judgments (1) 63:3 July (23) 7:16 8:2,20,25 10:7 22:22 23:8 24:4,13 24:18,24 25:14,14 25:18,19 26:7,19 27:5,13,25 41:6,17 182:14 June (4)
--	--	--	---	--

25:2,7 29:20 163:22	128:22 129:8	leader (1)	28:21,24,24 29:4,9	61:16 87:11 98:14
K	Kristin (5)	38:25	30:6 149:4,7,10,16	108:4 110:16
Karen (1)	8:7 9:8 77:9,16	leads (1)	149:18 150:5 156:2	112:18 142:9 143:9
32:18	124:23	71:13	161:9 185:15	153:4 176:21
keep (2)	L	learn (1)	listed (7)	looks (2)
30:21 60:18	lab (3)	172:23	14:19 88:18 147:24	24:4 25:20
keeping (1)	151:17 153:3 154:22	learned (1)	156:21 160:7	lost (1)
132:16	lab's (1)	95:23	169:18 185:4	8:16
kept (1)	152:10	learns (1)	literature (5)	lot (7)
26:19	label (3)	128:12	12:3,7,11,22 119:16	30:19 39:2,7 152:7,8
Kevin (3)	154:2,20 155:20	leave (3)	litigation (14)	159:2 177:2
2:3 3:21 9:21	labeling (35)	55:11,14 130:23	36:9,24 37:8 38:7	Luci (5)
keyboard (1)	42:18 43:3,12,15	leaving (2)	40:7,12,15 41:18	8:7 9:5 29:2 74:20
174:10	44:22 46:18 49:17	49:24 50:2	45:25 46:17 53:10	75:21
kind (6)	49:20 54:12 55:20	led (1)	61:8 178:7,16	Luer (3)
20:16 34:7 128:3	58:16 59:5 60:22	91:7	little (11)	86:14 133:2,24
130:7 147:15	62:17,22 83:18	left (2)	21:14 22:15 27:6,17	M
169:10	149:18 150:10,15	41:7 137:25	41:2 50:18 90:19	M (5)
Kings (1)	150:17,23 151:2,9	legal (3)	100:17 119:9	4:10 171:14 175:8
2:5	151:12,20 152:7	3:14 53:10 91:22	120:25 171:21	179:17 180:12
Klimowicz (3)	153:15,19 154:3,15	legally (1)	LLC (6)	Machines (1)
55:14 112:3,6	155:12 160:15,16	35:25	1:16 3:12 35:21 36:2	40:19
know (94)	162:8 165:14	let's (5)	36:6,16	magazines (1)
5:10 6:9 7:14,23 8:6	labels (6)	71:23 143:2 155:22	Lock (3)	152:24
18:8 19:5 23:9,16	151:24 153:22 154:8	166:10,10	86:14 133:2,24	maintained (1)
23:20,22 24:8,25	154:9,25 155:21	letter (8)	lockage (1)	56:21
27:6,7,11 29:18,20	laboratory (1)	6:20 22:21 66:8,22	15:3	making (3)
30:10,13 31:2,16	45:2	108:13 164:12,19	logged (1)	63:2,9 67:18
32:12,15 34:21	labs (1)	182:14	26:22	malfunction (2)
38:11 39:12 40:9	175:17	letters (1)	long (4)	65:7,23
43:22 44:14,21 45:7	laid (3)	66:19	21:22 22:12 38:11	malfunctioned (1)
45:9 48:25 50:6	16:25 78:25 137:6	level (1)	40:17	65:11
56:17 57:23 60:11	language (2)	108:21	long-term (1)	management (4)
60:17,20 65:16 66:3	153:14,17	lift (1)	172:11	41:13 59:11 98:22
66:7,11 69:12 71:3	Lapina (1)	157:7	look (27)	134:15
71:6,14 72:20 73:22	41:8	light (1)	14:13 19:21 20:22	manager (1)
87:18 88:11,20	lapse (1)	152:2	28:18 33:8,9,12	38:19
89:25 92:4 95:15,15	54:19	lighting (5)	49:18 87:24 107:22	managerial (1)
96:3 101:17 102:6,7	lapsed (1)	149:10 160:2,2,3,4	113:19 125:2	38:21
103:3,4 104:15,19	128:14	limitations (1)	136:18 141:12	manipulated (1)
109:24 110:23,24	laptop (3)	173:20	142:21 143:16	155:10
110:25 112:6	7:9 8:11 30:18	limited (7)	144:4 155:22	manner (5)
113:12 119:4	larger (1)	53:17 107:14 139:21	156:24 166:11	15:9 63:15,19 78:22
123:18 126:7,9	177:5	167:17,18,25 168:5	167:3 168:22 169:3	136:21
127:19,20 135:18	late (5)	Line (8)	169:8 172:8,13,17	manual (6)
136:20,23 140:7,15	16:15 66:13 112:20	184:8,10,12,14,16,18	looked (26)	73:12,23 74:3 113:19
141:2,3 142:11,17	151:14 152:19	184:20,22	15:11,23 16:2,13,23	128:5 136:12
145:19 155:18,20	Law (1)	lines (2)	17:3,6,15,19 20:17	manuals (2)
161:23,25 173:10	1:16	174:19,20	31:18 44:20 45:5	60:8 162:20
176:6 180:15	laws (1)	link (2)	63:25 66:19 70:12	manufactured (2)
knowledge (6)	152:20	82:9 83:8	108:7 109:13	60:15 86:9
60:14 82:23 94:15	lay (1)	liquid (8)	116:20 132:15,18	manufacturer (6)
95:5 112:25 185:13	16:10	92:19 94:24 97:9 99:7	142:12 151:22	47:10 61:5 107:5
known (5)	lead (3)	99:13 113:25 114:6	162:19 177:6,11	111:17 154:13,23
92:24 93:4 117:2	86:16 114:4 136:15	135:9	looking (13)	manufacturing (1)
		list (15)	31:3 33:16 34:10	

44:5 March (1) 87:10 mark (12) 5:23 7:10 9:14 10:11 10:11 22:19 28:5 32:21 93:21 120:7 141:19,21 marked (14) 6:4 9:24 10:16 12:25 23:3 28:10 35:3 120:13 123:14,21 123:24 141:25 142:22,23 market (11) 1:17 64:6 111:9 131:15,17,18,19,21 131:23 132:11,17 marketed (1) 86:23 marketing (2) 38:23 139:5 Master's (1) 51:21 material (14) 16:13 17:5 29:21 31:17 34:25 55:13 82:20 85:8 88:18 94:16,23 104:18 132:21 163:23 materials (18) 6:23 7:11,15,17,18 10:25 11:14 22:9 28:16,21 29:5,24 30:7 31:12 60:9 133:5 163:21 164:4 matter (15) 3:5 11:21,21 14:16 18:10 19:11,12 20:9 21:5 46:5,8,10,14 68:14 93:24 matters (1) 67:7 McConnell (6) 102:11,16 103:12,22 103:24 104:5 McConnell-Montal... 29:16 mean (12) 13:16 25:3 49:23 67:15 80:3 91:23 127:21 145:18 163:15 168:17 170:17 171:25 means (2) 65:3 133:10	meant (1) 79:25 mechanical (1) 173:7 medical (125) 7:8 13:4,6 16:4 30:7 30:11,14,16,24 31:3 31:19 33:6,10,11,17 33:22 37:13 42:10 42:15,16,20,23 43:3 43:7,8,10,16,19 44:5,7,15 45:4,8,10 45:13,16,19,20,22 45:24 46:8,16,18,22 46:25 47:5,24 48:18 50:10 52:6 53:25 54:5,8 55:2 56:8,9 56:12,14,15,18,22 57:2,5 58:16 59:5 59:12 60:12,22 61:3 61:4,13,15,20 105:22 107:4,9,13 120:17 150:5,8 156:3,14,17,19,23 159:7 160:10,13,25 161:2,7,8,13,13,17 161:20,22,24 162:2 163:21 164:2 166:6 167:5,8,16,18 168:24 169:4,11,14 169:16 174:3,7,14 176:13 178:2,15,19 178:21 179:2,6,7 180:6,17,21 medication (29) 42:18 44:22 149:18 150:9,15,17,23 151:2,8,9,10,20 152:6 153:6,11,12 153:15,15,20,21,25 154:15,25 155:8,15 155:20 160:14,16 179:5 medications (3) 152:19 154:8 155:15 Medtronic (68) 1:9 3:6,24,25 14:20 14:24 15:5,24 16:6 16:14 17:7,11 18:6 34:4,9 49:5,11,16 49:19 50:9,13 66:11 78:25 79:14 81:7 86:3 88:15 89:6 90:12 93:5 94:11 95:12 97:24 98:19 102:9 103:17 106:3	106:7,10 107:18,20 107:24 109:23 111:6,22 113:9 115:11 119:8,14 127:17,21 128:5 129:9 131:16 132:9 133:15,16 138:18 145:16,20,25 146:15 147:4 162:18 163:3 165:12 166:17 170:6 Medtronic's (17) 75:10 79:18 82:4 86:21 94:15 95:14 95:16 98:12,22 106:18 111:17,17 134:15 164:23 165:5,10,17 member (3) 159:10,13,19 members (2) 74:16 117:3 memberships (1) 159:10 membrane (5) 55:13 85:25 132:14 132:18,21 membranes (2) 55:17 132:8 memorized (1) 70:7 memory (4) 34:22 75:18 172:11 172:12 mention (2) 117:17 133:2 mentioned (10) 9:3 10:3 27:16 72:24 82:19 119:9 123:8 134:2 172:20 178:19 mentioning (2) 73:2 133:24 Merrell (49) 2:11 3:23,23 4:12 5:22 6:6 9:14 10:2 10:10,18 22:19 23:5 28:5,12 50:22 51:9 56:2 63:7,17 64:13 64:16 66:17 70:10 80:19 84:20 87:2 92:6 96:2,14 99:2 100:13 101:16 104:14 114:19 115:2 120:7 121:7	141:17 142:4,8 145:15 146:9 167:2 171:8 175:10 180:14,23 181:13 182:5 message (3) 106:11,16,21 met (1) 4:16 method (3) 14:10 88:15 89:6 methodologies (2) 116:12 161:6 methodology (2) 118:15 174:25 methods (1) 175:17 mid (1) 151:14 mid-1990s (1) 151:3 mid-90s (1) 150:12 migrates (1) 126:18 Miller (2) 1:19 183:14 mind (2) 34:19 110:19 minimal (1) 143:21 MiniMed (2) 3:25 49:6 minimize (1) 127:9 minimized (2) 113:23 127:12 minimizes (1) 127:4 minimum (1) 154:16 minutes (2) 21:25 144:25 Mischaracterizes (1) 97:16 misreading (1) 150:25 mistake (1) 103:23 mistaken (1) 87:12 mistakes (1) 173:13 misuse (1) 136:10 mitigate (1)	128:6 mocked (3) 154:7,8 155:2 mode (2) 176:20 179:24 model (2) 18:11 19:6 modes (7) 175:23 176:19 178:11 179:22 180:5,16,20 moment (3) 7:11 34:20 58:7 moonlighting (1) 41:12 morning (5) 3:20 4:13,15 69:11 170:16 motor (2) 106:15,20 motorcycle (7) 148:6,9,12 157:20,22 158:2,5 motorcycles (1) 158:8 Move (1) 157:9 moved (2) 108:8,10 moves (1) 172:19 moving (2) 75:4 88:9 multiple (3) 5:15 94:7 153:22 muscle (1) 172:19
<hr/>				
N				
<hr/>				
N (12)				
2:2 4:10,10 171:14,14				
175:8,8 179:17,17				
180:12,12 182:2				
name (6)				
3:13 155:15,16,19				
184:2,3				
narrow (1)				
114:9				
National (1)				
158:17				
nature (1)				
144:3				
NE (1)				
2:14				
necessarily (1)				
13:24				
necessary (2)				

61:22 119:22 necessity (1) 163:17 need (16) 5:9 11:11 20:10 75:22 78:9 86:24 88:10 90:11 117:15 130:3 130:5 138:24 152:16 154:17,18 170:3 needed (7) 90:15 129:24 138:18 138:19,20 144:15 164:25 needs (3) 48:4 118:21 159:15 neurologist (1) 53:22 never (29) 42:9,12,13,14 43:2,6 43:10,14 45:15,18 46:23 47:3,7 54:25 56:21 58:14,15 60:24 61:2 86:23 99:17 116:10 131:6 131:21,23 133:4 176:12 177:25 178:14 new (2) 122:8 135:15 newspapers (1) 152:24 night (7) 68:24 69:4 75:19 76:18 80:12 96:9 99:8 NJ (1) 2:6 non-billable (3) 38:15,17 39:7 non-leading (1) 40:22 non-litigation (1) 36:19 non-prescription (1) 42:18 non-videotaped (1) 35:16 nonprescription (1) 150:16 nonresponsive (3) 84:22 99:4 123:12 North (4) 45:2 51:11,21 159:24 Notary (3) 1:20 183:15 185:25	notation (1) 24:2 note (12) 64:9,13 108:25 112:22 120:17 124:17 133:3,9,15 134:20 135:16 146:18 noted (11) 13:8 16:19 26:13 94:5 109:6 134:13 135:2 136:7,11 138:12 185:15 notes (5) 68:21 70:2 100:16 121:12 183:6 notice (10) 1:15 5:18,24 6:11,24 7:5 10:5 29:9 35:22 182:10 notification (4) 163:22 164:2,10,19 number (42) 1:23 3:3,9 6:15 11:19 11:21 12:5 18:11 19:6 50:25 51:7 72:16 100:5,12 109:9 110:11,12,13 110:17,22,24 111:2 122:11 129:12,20 131:14 132:5,6 140:18 141:9 145:6 145:13 151:18 160:5 167:3,11,14 168:25 173:23 176:7 181:4 182:9 numbers (6) 70:6 109:7,8,17,18 168:18 <hr/> O <hr/> O (5) 4:10 171:14 175:8 179:17 180:12 object (3) 84:21 99:3 123:11 objection (13) 55:23 64:10,14 66:6 85:22 91:21 95:20 96:10 97:15 101:11 104:8 146:3 166:20 objections (1) 183:4 obvious (1) 146:6 obviously (3)	5:10 53:19 146:5 occasions (1) 139:25 occur (4) 73:11 96:19 97:12 114:8 occurred (18) 61:13 74:6 76:25 77:3 81:2,5,19 82:9,18 83:6,12 88:5 91:14 92:17 95:7,10,18 97:23 occurrence (1) 108:21 occurring (8) 73:9 86:11 94:2,14 97:20,21 98:10 113:11 off-highway (1) 157:22 off-road (1) 158:5 offered (2) 153:12 158:2 offering (1) 85:19 offhand (25) 12:4 23:15,22 34:25 39:12 46:22 56:16 56:20 57:6 58:19,25 59:9 60:23 66:25 69:14,25 104:12 119:19 127:20 142:11,17 147:5 162:10 180:18,22 office (1) 38:22 Offices (1) 1:16 Oftentimes (1) 53:6 oh (8) 103:7 114:20 133:13 134:6 142:14 143:3 168:17 177:10 oil (1) 114:6 okay (128) 5:3,12,22 6:15 7:10 8:18,24 11:9,13 12:19 13:9,18 18:2 20:2,22 24:22 25:22 26:2,4 29:23 32:18 36:11,23 41:5 45:6 46:10,14,23 47:17 47:23 48:16 50:8	52:18 54:25 55:11 55:19 56:21 57:19 58:6,20 59:3 63:8 63:18 64:13 65:2,13 65:18 66:18 67:3,12 67:18,25 68:15 69:20 70:5,11,16 71:3,23 72:8 73:4 73:10,18 76:5,20 77:2,15,25 78:16 80:2 82:11 83:3,15 84:10,21 85:9 87:13 88:4,16,21 89:18 90:19 91:4,16,19 97:8 99:3,16,23 100:14,23 101:8,21 103:6 115:10 121:8 121:19 123:2,11,13 124:2,3 130:9 133:6 134:2 141:9 142:7 142:14 143:16 144:4 145:25 146:10 150:20 155:24 160:5,17 161:9 166:14 167:3 168:14 169:8 170:23 171:8 175:5 175:19 179:14 180:10,23 old (1) 109:10 older (2) 151:21,21 once (3) 97:24,24 152:12 ones (8) 20:19 31:14 33:7 56:10 60:2 61:9 135:15 156:5 opened (1) 33:13 operation (3) 157:7,7,13 operator (1) 156:25 opined (1) 134:6 opinion (18) 55:5,7,10 67:19 73:13 73:19 78:8 81:15,22 85:19 111:21 112:8 115:11 133:21 134:3 140:2 146:5 166:15 opinions (64) 11:16 12:13,23 13:23	14:3,7 16:22 17:14 29:6 33:18 34:15 49:2,4,10,16 54:2,5 54:8,16 62:13,18,19 62:21 64:3,21,23 65:6,10 67:4,14 74:10,13,17 80:6,18 81:14 86:25 91:25 102:20 104:6 121:4 123:19 131:11,14 132:19,20,24 138:4 139:14 140:11,23 162:8,24 165:7,9,11 165:17 166:24 169:12,22 170:14 170:21,25 171:4 opportunity (1) 76:14 opposed (3) 117:6 174:7 180:7 opposite (1) 129:11 order (6) 108:14 109:6 110:2 135:7 151:24 154:19 ordering (1) 154:19 organization (1) 44:3 orientation (6) 75:9,15 76:7,17,22 77:5 original (2) 21:11 103:23 outcome (1) 98:16 outside (7) 11:13 12:13 113:4 158:22 167:14 176:14 178:16 over-the-counter (10) 44:20,22 46:20 151:9 151:20 152:6 154:7 154:14 155:11 160:14 over/underdelivery ... 84:6 overall (2) 36:22 178:11 overdelivery (13) 71:4,13 72:3,18 74:7 82:13,21 85:2 98:17 135:12,22 136:15 137:10 overinsulinization (1)
---	---	---	--	--

135:11 overlapped (1) 41:15 overview (1) 147:15	120:24 participants (4) 120:19 121:10,13 122:2 particular (13) 20:3 31:12 33:17 66:4 137:5 145:16 146:12,13 147:12 148:8 153:11 170:5 175:3 particularly (2) 53:13 131:8 Partly (1) 38:18 parts (5) 117:25 135:23 137:18 141:6 178:12 passed (1) 87:22 patent (2) 161:19,21 patents (2) 161:10,12 patient (7) 79:5 110:16 125:8,13 143:19 164:12,18 patients (5) 77:10 110:11,13 117:12 164:20 pedestrian (1) 148:23 peer (1) 39:3 pending (1) 121:22 Pennsylvania (1) 1:18 people (12) 117:12 118:15 122:6 122:10,23 130:15 145:23 167:21 172:4,8 173:11,13 people's (2) 39:4 172:13 perceive (1) 172:15 percent (11) 36:25 37:7,8 38:8 40:14 41:24 110:2 131:2,3,4,5 percentage (8) 41:20 109:15,16,19 109:21 110:9,19,20 perfect (2) 131:2,4 perform (1)	24:14 performance (1) 148:11 performed (5) 47:7 60:24 61:2,7 102:8 period (1) 45:6 permission (1) 41:13 personal (2) 158:21,21 personally (1) 152:14 perspective (4) 53:11 174:3 178:23 179:9 Ph.D (2) 51:10,14 pharmaceutical (2) 152:21,21 Philadelphia (3) 1:17 3:12 38:22 philosophy (1) 51:17 phone (2) 106:23 174:11 photographs (1) 70:24 phrase (1) 150:7 physical (1) 172:18 physically (1) 20:6 physicians (1) 74:13 pictograph (1) 134:20 Piedmont (1) 2:14 pinnacle (1) 31:20 pistol (1) 158:20 piston (1) 124:12 place (4) 77:10 93:3 111:18 138:9 placebo (1) 155:3 placed (2) 106:3,24 placing (1) 75:3	plaintiff (9) 1:7 2:7 3:22 21:8 41:20,25 42:7 45:25 61:7 Plaintiff's (1) 23:13 plaintiff/defendant ... 41:23 Plaintiffs (2) 23:7,17 planned (1) 170:16 planning (4) 49:2,8,14 165:16 please (5) 3:18 4:3 171:20,21 181:10 plus (3) 36:25 37:7 40:14 PMA (4) 48:12 62:2,10,11 point (19) 32:6 50:20 57:9 58:12 59:4 63:8 68:16 73:22 88:20 90:25 92:5 93:8 108:4 112:19 119:17 128:14 130:4 138:21 179:11 pointed (4) 57:7 92:11 94:20 98:20 population (14) 110:16 116:10 117:2 117:3 118:16 121:6 121:15 122:6,11,19 122:24,25 151:22 154:6 populations (1) 123:4 portion (2) 144:11,17 portions (1) 104:16 pose (1) 174:9 positions (1) 39:9 possibility (2) 126:14,25 possible (4) 97:9 114:6 121:2 139:10 post-2013 (1) 17:7 post-2014 (1)	138:23 post-incident (3) 30:25 34:16,18 post-market (1) 105:22 post-treatment (1) 31:21 potential (26) 15:3,8 47:25 54:18 78:20 79:2 80:22 82:12,21 83:2 84:5 84:13 85:2 86:6,16 108:5 112:5,13 117:12 130:23 135:21 136:5,6 168:22 177:21 178:22 potentially (1) 114:4 Powered (1) 157:5 practical (1) 156:7 practice (5) 38:25 39:2,6,6 46:9 pre (3) 17:7 30:24 31:21 pre-2000 (1) 86:14 pre-pump (4) 141:20 142:18 143:6 182:17 pre-pumps (1) 142:24 preceded (2) 92:25,25 preexisted (2) 79:12,22 preference (1) 90:12 preferred (3) 88:14 89:6 129:10 preliminary (4) 4:17 5:4 14:14,16 premarket (1) 47:4 premium (1) 35:13 preparation (5) 6:13 10:3 21:15,20 26:5 prepare (8) 5:13 21:13 22:3,6,9 25:14,18 43:7 prepared (5) 38:16 102:24 103:3,4
---	---	---	--	--

170:23 preparing (3) 22:17 25:23 27:19 prescribed (2) 93:2 136:21 prescription (12) 42:17 44:19,23 79:13 79:22 150:16,17 151:10 152:18 153:6 155:8 160:15 prescription-type (1) 46:21 present (5) 2:20 76:11 99:11 151:23 153:5 presentations (2) 160:6,10 presented (1) 155:10 pressure (1) 113:3 pretty (1) 23:19 prevented (1) 86:10 prevention (1) 156:9 previously (2) 57:20 143:7 primarily (5) 40:7 54:11 158:13 160:20 165:20 primary (1) 166:16 prime (10) 73:12,18,23 74:3 109:3,21,21 110:20 111:4 128:22 priming (1) 72:24 principal (1) 37:23 principle (3) 120:4 122:13 123:9 principles (11) 138:8 156:11 166:18 168:10,19 174:12 174:18,22 175:12 179:12,13 prior (20) 14:15 20:24 22:16 24:13,18,21,24 36:4 37:16 39:24 40:18 40:24 46:9,14 51:20 58:10 76:18 99:14 109:4 120:16	privy (1) 95:24 probably (17) 5:3 18:25 22:14 31:10 36:20 37:11 41:22 65:3 70:5 71:10 140:24,25 141:8,10 151:6 175:17,21 problem (4) 129:16 130:12 164:20 176:22 problems (1) 66:10 procedure (2) 88:14 126:16 proceedings (1) 183:4 process (14) 45:16 47:4 48:18 62:3 62:7,8 77:17 105:16 105:19 112:21 120:23 127:25 128:20 172:9 processes (1) 63:23 produce (1) 103:8 produced (5) 15:18 21:8 69:2 120:9 123:16 product (56) 11:24,25 14:21 16:3,5 16:7,15 17:10 48:13 53:12 60:7,8 61:3 61:13,13 63:25 64:5 64:6 80:7 81:11 82:5 83:24 86:4,22 92:24 111:8 112:16 115:20 116:25 119:14 122:8,9 128:8 131:25 132:13,16 133:10 136:10 139:2,6,9,11 146:12 149:21 159:18 167:24 168:3,6 174:8,11,14 174:15,19,23 175:24 180:8 products (28) 44:8 45:4 46:22 52:25 62:23 63:10 64:12 117:5 122:4,17 146:7 167:20 168:2 168:4,11,20,21 169:15,17 170:8 172:25 173:8 175:3	176:9 177:18,23 178:22 180:2 professional (4) 53:11 158:14,25 159:9 professionals (4) 159:25 172:3,22 173:3 professor (2) 175:15,20 professors (1) 175:13 program (2) 105:22 159:17 programming (1) 70:22 project (3) 40:10 47:14 152:12 projects (4) 36:21 44:24 152:13 153:4 promoting (1) 39:6 promulgated (1) 152:6 proper (11) 15:24 79:9 81:8 88:6 111:15 112:8 113:6 117:9 118:14 119:7 134:7 proposals (1) 38:16 protection (2) 158:21,22 prototypes (1) 118:2 provide (21) 15:6 29:6 39:15 49:16 53:25 54:4,7 65:5 76:14 79:18 81:10 109:16 110:9 124:8 133:23 134:3,19 135:17 139:18 165:7,17 provided (45) 7:12,15,24 8:5,9 10:22 11:14 12:8,25 13:21 14:24 15:16 16:13 17:6 18:3,20 22:21 27:16 31:15 31:18,24 57:21 58:4 60:15 75:2 79:6 94:17 109:17 113:17 114:12 125:13 126:2 127:17,24 133:17	134:21 135:20 140:4 162:13,17,20 162:21,24 163:8 171:3 providing (11) 49:2 54:15 55:4,7,10 65:10 110:10 118:22 131:11 163:11 165:11 prudent (1) 111:16 psychology (4) 51:15,22 52:2 53:8 Public (4) 1:20 149:3 183:15 185:25 publications (2) 160:6,9 published (2) 152:5 161:10 pump (86) 18:7,9,10,12,13,15 19:13,18 20:4,7,12 20:24 21:3 33:24,25 34:4,11,11 60:16,19 61:25 64:18,20,21 64:23,25 65:6,11,12 65:20,25 66:4,24 68:9,13,24 69:2,2 69:13,22 70:13 71:2 71:15,17,22 72:2,5 72:9,17,21 75:9,25 76:3 79:7,12,13,16 79:23 86:13 90:5,7 93:2 105:2,10 106:12,16 110:11 110:13 113:19 114:12 124:5,12,20 125:15 126:4 128:5 135:24 141:21 143:8,11,17 162:22 163:3,9 165:14 182:19 pumps (1) 46:6 purpose (4) 118:24 119:12,23 147:11 purposes (1) 122:18 pursuant (1) 1:15 put (15) 5:17,19 28:2 67:11 104:6 111:8 117:25 126:21 128:24	131:15,22 138:20 147:13 155:16 176:4 putting (2) 117:21 132:10 <hr/> Q <hr/> qualifications (1) 65:14 question (16) 5:6 19:2 40:23 47:20 50:4 57:19 89:15,17 89:19 90:19 91:22 92:15 121:18,21 144:14 158:10 questions (16) 4:17 10:5 11:11 14:11 14:18 16:23 28:13 56:4 58:3 90:18 147:7 171:9 173:24 179:15,22 180:24 quick (3) 124:5,16,19 quickly (2) 171:12 179:20 quite (1) 144:15 quote (2) 120:18 121:12 quote/unquote (4) 112:18 115:19 117:18 118:6 quoted (1) 123:7 <hr/> R <hr/> R (1) 2:2 Rabi (1) 32:24 Rachel (1) 11:21 ran (1) 117:18 Randy (5) 15:17 33:3 103:19 112:24 146:17 rare (2) 108:22,22 rate (4) 35:7,8 85:4,11 ratio (1) 132:3 Raymond (1) 157:8 read (11)
--	---	---	--	---

9:12 31:23 32:15 118:12 135:3 144:11,13,17 162:3 185:2,11 reading (1) 88:22 real (3) 71:10 171:12 179:20 realized (1) 129:8 really (10) 65:14 80:6,9,13,25 83:16 84:24 87:20 89:19 178:20 reason (13) 87:20,25 131:22,24 184:4,8,10,12,14,16 184:18,20,22 reasons (1) 185:5 recall (61) 9:2 18:11 21:4 22:18 23:12 30:16,22 32:6 32:10 33:9,20,21 34:2,25 40:13 44:16 44:19 45:3 46:7,7 46:12,21 57:6,16 58:2,8,12,19,25 59:13 62:8 66:8,12 66:22 67:2 69:25 73:2 75:17 76:15 77:15,19,21 87:17 89:14,16 90:8,17 99:21 103:7,10 104:12 110:12 118:11 143:10,14 144:22 156:16,19 162:9 163:11 174:4 receive (1) 164:13 received (10) 8:6,20,21,25 28:25 51:20 76:2 97:24 103:24 106:10 receiving (2) 9:6 164:12 recess (3) 51:3 100:7 145:9 recognition (1) 164:24 recollection (3) 27:21 88:20 185:14 recommendations (3) 17:24 54:23,24 recommended (1) 33:24	record (16) 4:16 50:25 51:8 58:5 64:10 69:8 72:6,10 100:4,11 142:15 145:6,13 181:6,8 184:5 recorded (4) 3:4 68:23 71:15,17 recording (5) 71:20 72:2,17,21 108:18 records (18) 7:8 11:10 17:12 23:23 26:20 30:7,11,14,17 30:24 31:3,19 33:7 33:10,12,18,23 68:25 recreational (1) 149:7 refer (1) 67:16 reference (13) 13:3,7 59:20 100:21 118:25 120:5 121:3 150:22 162:11 163:20 167:11,14 170:3 referenced (10) 6:12 12:14,15 81:22 95:11 100:19,23 105:6,6 164:3 references (15) 12:5 13:7 59:22,24,25 60:2 119:2 166:8,11 166:16,23 167:15 167:19,22 168:7 referred (1) 53:7 referring (2) 150:19 166:9 refill (3) 74:25 75:19 88:25 refilled (2) 75:14 93:13 refilling (11) 77:17 88:7 89:13,24 92:11 96:17 99:18 114:14 124:10 127:25 144:21 refills (1) 87:15 regard (9) 39:5,20 42:16,17 43:19 48:12 77:4 89:7 165:24 regarded (1)	133:12 regarding (32) 15:2,7 23:13 25:11 30:24 42:15,19 49:2 54:8 55:8 62:22 64:18,20,21,23 66:9 66:23 68:23,24 76:16 79:9 86:25 106:9,23 107:20 112:7,25 119:3 121:4 134:16 163:3 165:17 regardless (1) 174:13 register (1) 72:16 registered (1) 36:3 regular (1) 181:9 regulation (9) 58:22 59:2,4 60:22 101:20,23 102:4,5 152:8 regulations (27) 47:9,13,19 48:2,4 49:6,11,25 50:11,14 56:17 57:4,10 58:16 101:7,9,13,15 102:2 152:7,8 153:8 154:13,15,24 165:13,18 regulatory (8) 48:11,15,17,20,24 49:3,22 67:10 relate (4) 156:2 158:24 160:25 161:3 related (21) 16:24,24 31:20 39:3,8 40:11 44:6 71:5 102:21 128:3 148:15 151:8 159:7 161:25 162:22 163:13 165:21 166:6 167:19 172:4 177:2 relates (2) 137:19 174:3 relating (2) 59:5 67:14 relevant (9) 20:11 33:15 34:2 81:7 81:13 156:23 162:2 164:14 169:7 reliability (1)	156:7 reliable (1) 129:15 relied (12) 11:15 12:12 13:10 17:8 20:8,11 67:3 74:18,20 104:23 114:13 116:20 relief (1) 46:20 relooked (1) 108:8 rely (9) 96:18 97:4 98:24 117:4 119:3 130:25 131:6 168:8 169:21 relying (9) 12:21 13:22 97:11 116:23 119:19 128:5 129:13 130:12 166:4 remember (8) 40:10 75:5 76:17 104:10 109:2,7,14 153:16 removal (1) 89:7 remove (4) 75:7 94:8 126:20 130:19 removed (8) 90:13,16 92:22 94:3 95:4 97:2 128:24 129:25 removing (8) 75:23 77:23 89:3 91:9 98:3,4 113:22 163:19 rendered (1) 140:2 repeat (2) 5:7 47:16 repeating (1) 122:13 rephrase (5) 5:7 47:22 48:7,9 150:25 report (91) 7:13,16 8:2,23 10:7 12:6,15,24 13:8,10 14:19 16:11,20 17:2 17:19 18:4 25:15,18 25:23 26:5 27:12,24 28:2,7,19 36:25 54:9,11 57:8,9 59:23 60:3,5 67:18	73:3 74:20,21 81:23 85:10 94:5 100:20 100:22 102:24,25 103:3,4,8,11,14,23 103:25 104:3,16,17 112:22 119:2 132:22,25 133:3,8 133:20 134:13,18 135:2,17 141:3 146:19 160:25 162:11,12,16,25 163:5,6,14 164:17 165:8,9 166:8,12 170:4,10,12,13,19 170:22,24 171:5,5 171:24 182:15 reported (4) 108:14 109:9 110:3 111:10 Reporter (4) 3:16 4:3 181:7,11 reporting (4) 3:16,18 72:2 108:18 reports (5) 104:7 160:18,20,22 161:5 represent (2) 34:8 121:14 representative (5) 106:20 118:16 120:20 120:22 122:19 representatives (2) 122:24 154:6 requested (2) 5:18 6:24 requests (1) 6:16 required (1) 164:24 requirement (3) 49:3 101:20,22 requirements (12) 16:11 49:7,17,20,22 50:2,11 63:22 101:5 101:9,18 154:20 requiring (1) 121:25 research (15) 14:14 43:24 44:6,21 58:23 150:14 151:8 151:18 152:10,10 152:16 153:7 154:21 172:3 175:16 researchers (1) 172:3
--	--	---	--	---

researching (1) 150:14	7:5	riders (1) 148:12	133:11 137:4,4	146:8
reservoir (101) 14:25 15:15 16:8	responsibilities (3) 38:21 39:3 178:10	riding (2) 158:4,5	148:23 149:4 156:8	send (1) 26:16
18:17,19 19:3,5,14	responsibility (1) 133:10	rifle (2) 158:17,18	157:8,14,18,20	sense (2) 5:7 47:21
19:18 20:5,7,13,18	responsible (3) 146:21 176:8,10	right (8) 18:25 89:19 136:19	158:2,6 159:3,11	senses (1) 172:5
34:5,12 62:5 66:4	result (8) 54:19 135:12,25	136:23 142:25	163:21 164:2 168:3	sent (1) 8:16
66:23 68:9 69:18	136:22 152:9	163:25 178:23	sample (2) 118:19 119:10	separate (2) 57:21 185:16
74:25 75:3,8,10,15	176:23,24 177:3	180:8	sampling (1) 122:22	September (3) 1:12 183:8,10
75:22,24 76:8 77:5	resulting (2) 15:21 97:10	right-handed (1) 137:25	saw (5) 66:9 68:21 87:6 88:11	sequence (1) 88:6
77:12,18,23,24	results (3) 34:14 117:8 118:23	risk (52) 15:24 45:18,21,23	129:3	series (2) 152:13 153:4
78:21,23 79:17	retail (1) 148:25	46:18 47:7,13,19	saying (1) 20:17	serving (1) 36:24
87:15,21 88:7,8,25	retractions (1) 57:25	59:11 60:24 61:3,6	says (5) 35:22 80:10 122:5	set (59) 15:2,14 16:9 17:23
89:2,7,8,13 90:12	reuse (1) 104:18	61:14,17,20 79:9	143:23 144:3	18:22 19:5,13,18
90:15 91:10 92:20	Revel (2) 124:5,20	81:8 85:24 111:16	school (3) 43:25 51:18 148:22	20:5,7,13,18 30:11
92:23 93:14,14 94:3	reversed (1) 76:7	112:8,9,23 113:6,24	science (6) 51:22 52:2 53:3	34:5,12 55:6 62:6
94:8,25 95:4,4	review (20) 20:11,22 27:23 29:6	127:4,9,11 130:21	171:25 172:2,24	66:4,12,23 67:23
96:24 97:2 98:3,7	29:17 32:8 33:12	130:25 131:7,25,25	scientific (1) 14:10	68:8,13 69:19 76:12
99:7,13,14,18,19	57:15 62:24 63:18	132:2,3,4 134:7,8	Scranton (1) 52:3	78:21 79:7,16,23
104:20 113:21,22	67:20 70:17 77:8	135:21 139:8,10	screen (7) 69:21,22 70:8,11,12	83:13 87:15,21 90:8
114:2,14 124:10,13	78:17 82:20 85:8	146:20 153:5 156:6	71:7 106:16	91:6 93:10,16 97:14
124:13 125:10,22	88:21 105:2 109:11	156:11 167:11	screens (1) 70:25	99:11 104:21 114:3
125:23 126:19,23	177:17	169:11,14,16,19	second (7) 15:23 79:8 129:18	115:14,16 124:5,9
127:2 128:16,24	reviewed (38) 5:19 6:13 9:5,9 11:15	170:2,2,7	143:18 144:5	124:14,15,16,20,20
129:5,23 130:20	20:19 21:6 28:16	risks (6) 47:25 137:15 139:4	161:16 166:13	133:18 135:14
133:19 134:12	29:12,16,19,25 30:2	153:10 172:15	section (7) 16:12,19 17:2,18	138:23 143:19,20
135:8,14 138:3,9,16	30:3,15 32:5,12,18	177:21	121:10 133:15	144:20 162:23
138:22 143:20	32:21,24 33:3,19	Rita (4) 8:7 9:11 162:4,25	160:17	163:4,10 165:15
144:21 147:2	34:3,15,24 57:14	Road (1) 2:14	see (28) 6:17,20 8:10 9:18	sets (3) 110:14,17,22
162:23 163:3,10,18	58:14,15,21 59:13	roadway (1) 160:3	16:5 17:15 28:22	setting (2) 148:24 149:3
165:15	102:14 103:21	Robson (8) 37:17,25 38:6 39:24	29:10,15 30:7 33:13	seven (1) 167:11
reservoirs (2) 66:13 113:17	104:20 105:25	41:7,7,17 147:14	60:6,9 70:20 82:21	severe (1) 135:13
residential (1) 148:24	123:18 142:10,18	rough (2) 181:9,12	82:22 85:7 110:10	sheet (1) 185:17
respect (42) 11:23 13:23 16:22	164:6	RPR (2) 1:20 183:14	110:13 118:3	short (3) 51:3 100:7 145:9
17:14,25 20:14	reviewers (1) 167:8	run (2) 36:13,15	119:13 124:6,22	short-term (1) 172:12
31:22 33:6 36:17	reviewing (5) 22:8 24:8 27:18 39:3		138:5 143:3 147:9	shortly (1) 152:19
53:13 55:20 57:4	58:9	S (2) 2:2 182:8	147:25 169:3	shot (3) 69:22 70:9,11
63:14 65:25 66:20	rewinding (1) 124:11	safe (2) 66:5 173:17	seeing (3) 34:2 75:5 77:15	shots (1) 70:13
67:7,22 75:10 81:14	ride (1) 158:8	safety (26) 54:22 60:7 62:15,23	seen (7) 76:5 89:21 90:21	
83:21 95:19 96:5,16	rider (2) 157:21 158:3	63:3,9,19 64:2,11	109:11 143:10,12	
97:13 102:22 104:4			143:14	
115:13,15 121:24			sell (1)	
127:22,24 138:3				
146:25 148:9,14				
150:9 153:14 163:8				
165:13 169:4 177:7				
180:20				
responded (1) 117:13				
response (4) 120:16 157:15 165:5				
165:10				
responses (1)				

show (3) 84:8 97:11 141:15	sold (2) 110:14,17	154:12,23,23 161:2 161:8,22 162:6,9	169:9,9,15,18,25 180:15,20	strike (11) 36:4 37:3 39:23 42:25
showed (1) 69:16	solution (3) 129:3 131:9,12	165:13,24 166:7,22 167:25,25 168:5,24	standpoint (4) 64:2,2 172:2,22	48:22 54:10 60:25 65:4 126:12 140:9
showing (1) 77:21	somebody (3) 24:9 120:2 130:14	169:7,9,10,14 176:23 177:7,13	stands (1) 58:4	170:12
shown (1) 98:19	sorry (26) 12:14 13:15,16 30:21	180:5	start (7) 3:3 9:4 71:23 77:19	studies (18) 45:5 102:10,15
shows (1) 94:22	47:15 48:8 49:23 60:17 104:3 105:17	specifically (44) 15:17 25:5,11 29:7	135:5 141:21 182:19	115:19,25 116:7,19 116:22,25 117:11
side (2) 36:14 155:14	106:14 114:20 121:17 126:8	34:9 44:21 46:12 57:7 62:19 68:16	started (45) 14:9 17:8 19:22 20:12	118:6 119:24 151:18 153:22
sight (1) 172:6	137:22 140:24 142:11,25 143:5	77:14 85:6,13 89:15 89:16,20 96:6	20:23,25 21:4,7 37:6 42:3 75:11	154:2,4,5,10
signal (4) 107:9,19 135:5,6	147:19,20 157:7 168:17 175:25	104:12 109:24 114:11 116:9,16,21	78:12 90:6,10,24 104:24 105:4,9,14	study (10) 117:19,21 118:10
SIGNATURE (1) 185:9	177:10,24	127:23 129:19 150:7,11 151:17	113:10 115:8 120:8 123:15,16,20 125:3	119:7,12 120:3 123:3 154:2 172:8
significant (4) 136:22 144:19 148:13	sort (12) 13:25 14:5 19:17 40:4	152:10 153:3,17 156:14,16 160:10	125:14 126:3 127:7 127:18,22 128:4	172:23
148:19	53:25 71:25 83:15 107:16,19 108:20	160:13 162:10 166:6 167:5,16,18	129:19 130:2,8,13 134:10 135:19	studying (2) 148:22 179:11
similar (6) 18:9,12 19:24 38:2	177:25 178:15	168:16 169:5 170:3 170:19	136:4,14 137:6,12 137:14 140:17	stuff (4) 31:18 123:7 155:11
76:4 142:21	sounds (1) 34:24	spend (6) 22:8,16 25:13,17	182:16	173:10
similarly (2) 104:25 135:20	source (3) 116:18 123:19 126:10	33:15 144:8	starting (3) 60:15 75:3 138:12	subbed (1) 175:20
simple (1) 120:3	sources (3) 82:12 114:2,23	spending (1) 30:22	starts (1) 124:11	subbing (1) 175:13
simply (1) 69:3	space (2) 148:24 157:19	spent (10) 22:12,14 24:3,23	state (10) 36:3 45:2 51:11,21	subject (6) 33:24,25 60:16,19
single (2) 154:12,12	spacing (1) 152:2	25:22 26:20,22 27:4 31:3 144:18	95:15 133:20 135:7 154:15 165:23	71:2 79:7
sitting (6) 46:15 49:9 59:3 66:2	span (1) 141:7	spill (1) 98:6	166:2	submission (2) 46:24 47:4
110:18 145:3	speak (8) 21:19,22 22:5 24:11	spoke (3) 5:20 22:2 106:19	statement (3) 67:19 76:15 150:21	submissions (2) 48:12,15
situations (1) 133:11	25:4 74:9 106:19,19	spoken (3) 24:20 74:12,15	states (4) 1:2 3:7 125:6 136:17	subparts (1) 6:20
six (4) 6:16 90:7,9 128:10	speaking (3) 21:16 24:9 56:11	sporting (1) 149:8	statistic (2) 109:11,14	subproduct (1) 174:19
size (2) 151:25 154:16	Specialist (1) 3:15	Spouse (1) 1:6	stenographic (1) 183:6	Subscribed (1) 185:22
skimmed (1) 31:25	specific (70) 13:2,7 16:10,11 18:19	squirting (1) 113:21	step (5) 89:3 125:2 129:20	subset (2) 168:2,5
skip (1) 5:4	18:21 19:6,16 20:18 27:20 33:10 44:16	staff (1) 41:13	136:20 137:5	substance (1) 94:24
slash (1) 41:7	47:24 56:9 58:19 59:2,20,24 61:16,18	stand (3) 57:18,20 104:5	steps (6) 16:11 86:5 89:12,24	subtype (1) 168:5
slip (4) 54:19 128:23 130:17	62:8 68:13 72:18 74:3 75:18 88:19	standard (17) 16:2,5,17 17:4,13,20	90:3,23	suggest (2) 90:22 95:9
148:18	115:4 118:25 119:15,18,20 120:5	59:14,21 60:13,21 64:4 86:13 134:22	stop (1) 129:6	Suite (1) 1:17
slipped (1) 128:15	130:7 133:21,21,23 134:4 136:18,20	169:10,13 170:6,9	store (1) 172:10	sum (1) 170:14
small (1) 36:21	145:20 146:15 147:3 150:5 151:12	standards (12) 17:23 59:18 165:20	street (2) 1:17 158:4	summary (1) 147:21
Society (4) 159:11,14,20,24	151:22 153:17	166:19 168:23	strength (1) 172:19	supplement (1) 103:22
				supplemental (4)

102:25 103:4,8 170:24 supplemented (1) 104:3 support (7) 92:9 93:13 94:18 98:22 120:6 121:4 166:23 supporting (1) 75:13 supports (1) 69:4 supposed (3) 31:15 94:7 116:6 sure (21) 7:20 11:12 12:17 23:19 28:20 47:20 48:3,9 50:4 99:25 124:3 135:4 139:7 139:12,15,22 144:2 145:2,23 166:13 171:23 surrounding (2) 80:24 83:19 surveillance (1) 105:22 Surviving (1) 1:6 Susan (2) 102:11 103:12 Suzanne (1) 29:15 swear (1) 4:3 switched (1) 9:20 sworn (2) 4:7 185:22 system (11) 66:10,24 111:14 115:16 117:23 137:16,17 146:13 168:6 174:13,23 systems (6) 156:13 167:20 168:4 168:21 172:25 173:16	172:6 take (26) 5:10 20:3 42:9 45:15 49:15 50:18 53:24 54:9 55:11 58:8,13 79:14 82:15 84:23 100:2 110:18 112:2 137:8 144:24 155:5 155:22 158:12 160:24 172:23 173:14 176:12 taken (12) 1:15 4:18 51:4 68:22 79:15 86:5 100:8 109:20 140:17 145:10 183:6,8 takes (1) 130:17 talk (1) 121:10 talked (3) 100:17 170:18,20 talking (2) 14:12 80:9 task (9) 75:19 112:23 117:24 128:12 130:4 137:5 137:18 176:18 177:2 taught (1) 175:16 TBV (1) 177:8 teach (1) 175:20 teaching (2) 175:12,18 team (1) 98:22 team's (1) 134:15 technical (6) 159:18 160:18,20,22 160:24 161:4 technically (2) 35:20 51:17 techniques (3) 174:13,22,25 technology (1) 161:18 television (1) 152:24 tell (7) 24:25 115:6 119:5 122:15 130:14 171:21 176:7	temporary (63) 67:14,21 68:10,18 69:5 71:4,5,12,16 71:21 72:4,6,11,19 72:23 73:6,14,20,25 74:5 78:2,13,19 81:3,4,18,24 82:3,8 82:18 83:5,11 84:25 85:4,11 86:17,18 91:7 92:13,17 97:10 102:19 107:20 108:5,23 109:5,22 111:4 112:4,12 113:11 114:15 125:16 126:5,11,15 127:9,12,16 163:15 165:6 177:13,16 ten (2) 27:9 167:15 tend (1) 141:2 Tennessee (2) 1:3 3:8 Terminus (1) 2:13 terms (4) 81:2 108:23 153:13 165:21 test (7) 78:9 120:18,19 121:10,13,14 122:20 tested (5) 14:7 16:17 17:11 68:12 78:7 testified (17) 4:8,24 51:16 70:16 77:13 93:22 96:11 99:17 102:11,15 104:23 106:9 112:7 124:25 128:19 129:2,22 testify (2) 76:14 99:12 testifying (1) 99:21 testimony (57) 17:12 18:3 35:10 57:16,20 70:17,20 70:23 74:19,21,24 75:12,21 76:4,6,16 76:25 77:3,9,16 87:5 89:11,14,20,21 90:21 91:4,5 92:9 93:7,12,15,20 94:11 95:9,22,23 96:8,18	96:21 97:5,16 98:10 98:25 99:6 103:18 105:3,8,12 106:24 107:22 109:12 139:18,20 144:13 144:18 171:6 testing (31) 14:2,5 16:21 34:3,7,9 34:13,14,16,17,22 68:8 97:23 112:19 115:17 116:14 117:15 118:14,18 118:21 119:11 120:18,23 121:11 122:14,16,21,22,22 128:21 161:6 thanks (2) 175:6 181:13 thereabouts (1) 25:21 thesis (1) 155:6 thing (8) 15:23 81:13 93:24 105:5 116:8,13,15 146:22 things (14) 5:4,15,16 16:2 87:4 92:3 100:15,15 122:5 130:15 151:23 172:4 173:12,13 think (70) 5:2,17,21 7:18 8:19 8:24 12:2 13:2,6 22:12 23:18 27:10 27:16 31:5,8 33:19 35:4 38:10 41:21 42:6 46:16,19 51:16 56:3 58:21 65:2 66:13 67:10 69:14 80:20 83:22 88:10 88:12 94:10 100:24 101:19,21 105:11 106:11,15 108:11 108:13,16 109:10 119:21 120:5 127:3 129:6 133:13 136:3 139:16,23 140:16 145:22 155:11 156:22 160:12 162:10,19 165:25 168:12 170:17,17 171:9 172:19 173:21 175:14,17 175:20,21	thought (5) 49:12 63:23 101:12 109:8 115:3 three (16) 14:17 22:15 27:7 28:18,22 31:5 35:5 100:12 130:16 139:17 141:7 144:8 145:7 168:7,12,18 throw (1) 135:14 thumb (3) 7:11,20 9:21 time (73) 5:9,11 22:2,8,16 24:3 24:5,22 25:13,16,17 25:20,22 26:3,4,12 26:12,13,14,20,22 27:4 30:23 31:2 33:15,16 38:10,13 38:14,15,17 39:8 40:17 41:8,14,15,16 45:6 50:24 51:8 57:13 60:14 71:9 76:12,18 86:8 90:25 91:2,12 99:18 100:4 100:11 102:4 105:17 109:3 111:22 117:18 127:13 128:23 131:3,5 133:14 134:17 144:19 145:7,14 150:13,24 151:4 153:18 162:15 163:25 181:4 times (16) 4:21,23,24 46:3 90:7 90:9 94:7 128:11 139:16,17,19,23 140:6,14 175:19 176:4 title (4) 37:21 66:24 124:4 147:8 titled (1) 167:7 titles (1) 39:8 today (15) 5:14 6:23 7:3 12:8,25 22:6,10 46:15 49:9 59:3 66:2 170:11,21 171:6 181:5 told (2) 128:12 170:11
T				
T (6) 4:10 171:14 175:8 179:17 180:12 182:8 table (4) 77:11,17,20,23 tactile (1)				

tools (1) 156:7	185:11	130:16 132:6	92:11 95:7 96:22	173:19 174:8
top (27) 11:19 76:9 77:12 88:8 89:2,8 92:19 93:15 94:24 96:23,23 98:7 99:14,19 111:14 113:25 124:17,19 125:10,22 126:23 127:2 129:4 133:14 135:8 138:22 163:18	transcription (1) 184:7	139:25 142:16,20 142:24 143:3 157:25 158:6	98:11,13 99:9 101:3 104:22 108:17 132:7	user (38) 19:22 20:12,23,25 21:3 52:24 53:13 98:3 105:2 116:10 118:16 119:24,25 120:2 121:6 122:6 122:11,19,24,24 123:4 125:4 126:2 127:16 128:9 130:5 130:14 131:2,4 136:19,21 137:6,23 149:24 154:6 164:25 179:10,11
topic (10) 16:23 17:14,25 52:17 52:20 67:13 86:25 112:7 132:19 144:22	transcripts (1) 29:10	two-plus (2) 87:11,13	understands (1) 63:13	users (12) 117:7,8 118:3,10,22 119:13 120:20 121:15 122:2,7,9 133:11
topics (2) 20:14 172:21	transfer (13) 75:8,24 77:24 89:8 90:14,16 94:3 97:2 98:5 113:22 126:20 128:25 130:20	Tylenol (1) 155:17	understood (2) 83:9 90:11	utility (2) 132:2,3
total (9) 22:14 25:20,22 26:4 69:16 71:7 110:21 176:8 178:3	transitioned (1) 172:12	type (12) 86:10 114:5 115:22 130:24,25 146:19 154:16 174:11,25 176:23,24 180:8	unique (5) 174:6 178:20 179:2 180:5,19	utilize (2) 20:4 21:7
totals (1) 71:6	TRAURIG (1) 2:12	types (10) 82:24 84:3 108:18 168:10 173:12,25 174:24 175:2 177:3 180:2	unit (1) 130:19	utilizes (1) 60:20
touch (1) 126:23	treating (1) 74:12	typical (1) 64:7	United (2) 1:2 3:7	utilizing (2) 77:16 166:16
Track (1) 52:2	treatment (2) 30:25 76:3	typically (3) 31:19 173:2 177:4	units (7) 69:16,17,20 70:21 72:25 73:13 78:22	
tracked (1) 107:24	remendous (1) 132:4	<hr/> U <hr/>	University (4) 45:2 51:11,21 52:3	<hr/> V <hr/>
tradition (1) 113:14	trend (1) 107:9	Uh-hum (2) 44:18 111:12	unresponsive (1) 93:11	vacation (1) 175:14
traditional (1) 36:15	trending (1) 107:4	unanticipated (1) 139:4	up-to-date (1) 10:21	vacuum (1) 146:23
train (1) 77:10	trial (5) 4:25 91:25 139:18 141:4,5	unattended (1) 15:20	update (2) 120:15 153:8	valid (2) 118:23,23
trained (2) 94:6 128:19	tried (1) 171:7	underdelivery (5) 79:3 136:2,6,16 137:10	updated (3) 10:8 103:25 159:15	validate (2) 116:11 117:16
trainer (2) 123:25 128:12	trips (1) 148:18	undergraduate (2) 148:22 175:16	Urgent (2) 163:21,25	validation (4) 47:8 117:16 121:11 121:14
training (31) 11:22 53:12 60:19 64:3 75:25 77:21 105:5,7 116:24 119:6,20 123:22 128:11 129:23 130:15 141:14,20 141:21 142:19 143:8,12,17 144:9 144:20 156:25 157:6,15,18 169:24 182:17,19	true (3) 42:4 183:9 185:12	underlying (1) 171:4	usability (32) 13:5 102:10,15 112:18,19 115:19 115:22,24 116:7,12 116:19,22,25 117:11,19,20 118:6 118:10,14,21 119:7 119:12,23 120:3 122:14,16,20,22 123:3,9 154:5 161:6	Vardi (1) 32:4
transcript (6) 29:11 88:13,22 105:25 183:9	try (6) 12:19 70:5 108:20 115:4 117:7 128:21	underside (1) 85:25	use (40) 15:13,13 33:24 55:20 58:17 59:6 62:22 79:17 80:23 83:18 92:24 93:4 96:20 98:24 113:9 114:11 118:10,19 119:13 119:25 120:18,22 121:25 122:6 134:13 135:15 136:9 137:16,21 140:12 150:7 155:13,19 161:17 167:9 173:16,17,19	various (4) 6:20 30:7 31:19 41:19
	TSG (2) 3:15,17	understand (18) 4:18 5:5,6 12:17 19:23 23:6 63:16 67:15 80:17 92:7 105:9,13 115:3 122:3 129:5 131:10 155:4 165:19		vehicle (1) 174:15
	tubing (3) 125:24 135:8,10	understanding (48) 23:10 37:22 55:9 62:4 67:24 68:2,2,4,6,17 69:5,15,23 70:25 72:5,9 73:8 74:4 76:10 77:7,25 78:4 78:10 80:20 81:17 82:7,23 83:7 84:2 84:18 86:7,12 88:12 89:4,12,23 90:2,4		vent (72) 15:4,8 67:15,22 68:11 68:18 69:6 71:4,5 71:13,21 72:4,7,7 72:11,19,23 73:6,15 73:21,25 74:5 78:2 78:13,20 81:3,5,18 81:18,19,24 82:3,8 82:18 83:5,11 84:5 84:7,25 86:17 91:8
	turn (4) 28:14 35:2 67:12 124:2			
	turning (1) 35:18			
	two (33) 11:22 39:8 43:18 46:6 51:7 57:7,21 58:14 58:22 59:6 87:9 88:4,23 97:25 99:11 100:5 101:25 103:9 109:17,18 113:20 122:5,11 128:2			

92:13,17 93:9 94:13 94:14,23 97:11,19 98:16 102:19 107:20 108:6,23 109:5 111:4,14 112:4,13 113:11 114:16 125:16 126:5,11,15 127:10 127:12,16 163:16 165:6 177:14,16 vents (10) 15:22 78:22 86:15,19 86:20 94:13 97:19 109:22 113:2 135:9 verification (1) 47:14 version (9) 13:4,11 21:7 95:3 100:21,24,24 124:18 147:14 versions (1) 113:20 versus (2) 3:6 41:20 vial (41) 75:4,7,9,16,23,23 76:9 77:6,11,18,20 77:22 88:8 89:2,9 90:13,14,17 91:9,10 92:23 93:15,15 94:4 94:9 95:3 97:3 98:4 99:19 113:3 125:4,9 125:21 126:21 128:15,17 129:2,24 134:12 163:18 Vicente's (1) 32:8 video (13) 3:3 50:23 51:8 75:5 87:6,8 88:11,17 100:4,11 145:7,14 181:4 Videographer (11) 2:20 3:2,15 4:2 50:23 51:6 100:3,10 145:5 145:12 181:3 videos (4) 94:20 97:25 98:20,21 videotape (5) 1:14 5:24 6:11 35:12 182:10 videotaped (2) 35:10,14 view (3) 62:15 111:3,7 Vigilante (219)	1:1,15 2:1 3:1,4 4:1,6 4:13 5:1 6:1,8 7:1 8:1 9:1 10:1,13 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 21:1 22:1 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 35:20,23,25 36:1,2 36:5,8,12,14,16,17 37:1,2,6,10,11,14 37:16 38:1,3,3 39:1 39:11 40:1 41:1 42:1,3,7,8 43:1 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1,10 52:1 53:1 54:1 55:1 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1 71:1 72:1 73:1 74:1 75:1 76:1 77:1 78:1 79:1 80:1 81:1 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1 96:1 97:1 98:1 99:1 100:1 101:1 102:1 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1 116:1 117:1 118:1 119:1 120:1 121:1 122:1 123:1 124:1 125:1 126:1 127:1 128:1 129:1 130:1 131:1 132:1 133:1 134:1 135:1 136:1 137:1 138:1 139:1 140:1 141:1 142:1 143:1 144:1 145:1 146:1 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1 162:1 163:1 164:1 165:1 166:1 167:1 168:1 169:1 170:1 171:1 171:17 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1	179:21 180:1 181:1 182:1,4 183:1,7 184:1 185:1,19 vision (2) 148:4,15 Vitae (2) 10:12 182:13 vs (1) 1:8 <hr/> W <hr/> W (1) 1:6 Wagner (1) 167:11 wait (1) 115:7 waited (1) 132:12 want (14) 9:4 28:14 56:4 67:12 80:17 87:3 114:9 122:10 131:6 144:24 171:17 173:18 181:8,12 wanted (8) 4:16 14:18 21:13 35:2 50:21 58:5 121:16 124:23 ward (2) 135:5,6 warn (1) 16:24 warned (1) 163:2 warning (16) 17:22 66:19 80:14 130:4 131:7 134:21 134:25 135:6 136:8 136:11,17,24 137:9 138:21,24 163:12 warnings (33) 11:25 14:25 15:6 17:5 17:16,21 43:7,11,15 43:21 44:6 53:15 79:19 81:10 128:6 133:9,18 136:25 138:16 140:3,12,23 147:25 153:14,20 155:14 162:7,13,17 163:9 167:22,23,25 wasn't (16) 49:2,8,13,13,18 50:5 65:17 71:10 82:24 83:9 86:19 89:19 123:24 154:23	161:8 165:16 watched (1) 88:17 watching (1) 75:6 water (1) 144:15 waterproof (3) 86:22 131:17,22 way (15) 12:20 37:4 67:11 81:21 112:15 116:8 118:4 119:7 126:13 129:9,11 144:10 145:22 165:25 166:10 ways (1) 107:25 we'll (3) 12:6 13:9 142:14 we're (5) 80:5 87:11 100:3 173:9 180:25 we've (4) 50:15 59:7 99:24 171:18 Weaver (9) 8:8 9:11 29:2 162:4 162:14,18,21 163:2 163:7 Web (1) 152:25 went (5) 20:2 62:9 110:7 129:22 152:14 West (1) 2:5 Western (4) 1:3,3 3:8,8 wet (1) 135:14 Wide (1) 152:25 wife (1) 87:22 William (193) 1:1,14 2:1 3:1,4,12,21 4:1,6 5:1 6:1 7:1 8:1 9:1 10:1 11:1 12:1 13:1 14:1 15:1 16:1 17:1 18:1 19:1 20:1 21:1 22:1 23:1 24:1 25:1 26:1 27:1 28:1 29:1 30:1 31:1 32:1 33:1 34:1 35:1 36:1 37:1 38:1 39:1 40:1	41:1 42:1 43:1 44:1 45:1 46:1 47:1 48:1 49:1 50:1 51:1 52:1 53:1 54:1 55:1 56:1 57:1 58:1 59:1 60:1 61:1 62:1 63:1 64:1 65:1 66:1 67:1 68:1 69:1 70:1 71:1 72:1 73:1 74:1 75:1 76:1 77:1 78:1 79:1 80:1 81:1 82:1 83:1 84:1 85:1 86:1 87:1 88:1 89:1 90:1 91:1 92:1 93:1 94:1 95:1 96:1 97:1 98:1 99:1 100:1 101:1 102:1 103:1 104:1 105:1 106:1 107:1 108:1 109:1 110:1 111:1 112:1 113:1 114:1 115:1 116:1 117:1 118:1 119:1 120:1 121:1 122:1 123:1 124:1 125:1 126:1 127:1 128:1 129:1 130:1 131:1 132:1 133:1 134:1 135:1 136:1 137:1 138:1 139:1 140:1 141:1 142:1 143:1 144:1 145:1 146:1 147:1 148:1 149:1 150:1 151:1 152:1 153:1 154:1 155:1 156:1 157:1 158:1 159:1 160:1 161:1 162:1 163:1 164:1 165:1 166:1 167:1 168:1 169:1 170:1 171:1 172:1 173:1 174:1 175:1 176:1 177:1 178:1 179:1 180:1 181:1 182:1,4 183:1 183:7 184:1 185:1 185:19 Williams (2) 1:16 2:4 wireless (1) 161:17 witness (21) 4:4 55:24 63:4,14 66:7 76:6,24 77:2 85:23 91:23 95:21 96:12 97:17 99:6 101:14 104:10 120:15 146:4
--	---	---	--	--

166:22 182:3 184:3 worded (1) 71:10 work (54) 24:14,18 27:13,21 35:9,19,20 36:8,9 36:11,18,22 37:2,5 37:8,16,25 38:2,8,9 39:4,23 40:4,8,14 40:15,24,25 41:18 41:24 42:19 43:25 44:6,13,18 45:13 61:23 140:20 141:11 148:24,24 152:4 153:13 154:11,21,22 158:25 159:5 160:21,23 173:4,4 178:9,16 worked (11) 19:23 40:18 41:5,11 42:9,12,13 44:24 46:7 117:4 151:13 working (2) 140:8 141:6 workplace (2) 149:4 174:15 workshop (1) 156:15 workshops (6) 155:23,25 156:10,18 156:20,22 workspace (1) 160:3 workstation (1) 160:3 World (1) 152:25 wouldn't (10) 52:15,18 73:19 87:19 96:6,7 111:9,10 155:16 178:25 write (3) 43:3 141:3 153:19 writing (1) 8:22 written (1) 74:22 <hr/> X <hr/> X (7) 4:10 171:14 175:8 179:17 180:12 182:2,8 <hr/> Y <hr/>	yeah (23) 41:4 67:9 68:19 71:10 74:2 75:17 76:10 80:20 89:15 91:23 97:17 101:14 103:7 110:23 113:12 127:19 137:13 140:24 143:23 145:2 155:5 165:16 171:11 year (10) 23:21 39:11 108:10 110:4,7,8,14 140:20 140:22 141:11 years (14) 38:11,20 41:19 46:13 87:9,11,13 88:4,23 107:24 130:16 132:12 141:7 159:3 yesterday (3) 21:21 22:14,17 YouTube (3) 94:20 98:20,21 <hr/> Z <hr/> Z535.6 (1) 60:7 <hr/> 0 <hr/> 08033 (1) 2:6 <hr/> 1 <hr/> 1 (6) 5:23 6:3,10 110:2 182:10 184:5 1:57 (1) 145:7 10 (2) 73:19 182:13 10:07 (2) 1:18 3:13 11 (4) 60:2 168:8,13,19 11:05 (1) 50:24 11:16 (1) 51:8 12 (2) 138:13,13 12:13 (1) 100:5 12:59 (1) 100:12 120 (1) 182:16	13 (2) 38:11 138:14 1300 (1) 1:17 132.7 (3) 69:17,20 70:21 14 (9) 1:12 75:14 96:5,17 99:8 132:12 138:4 183:8,10 141 (2) 182:17,19 147847 (1) 1:23 14971 (1) 59:10 14th (14) 69:17 74:8 75:20 76:22 77:4 78:14 81:6,20 92:22 93:17 95:8 97:7,13 98:15 15 (3) 21:24 132:12 138:5 150 (1) 4:23 1515 (1) 1:16 15th (10) 69:13,18,21 74:8 76:18 78:14 81:6,20 91:6 95:8 16 (1) 132:12 171,179 (1) 182:6 19102 (1) 1:18 1990s (2) 16:15 152:20 1992 (1) 167:11 1997 (3) 41:6 44:13 45:7 1998 (1) 40:20 1999 (2) 93:7 152:7 1999/2000 (1) 132:18 <hr/> 2 <hr/> 2 (7) 9:15,23 12:8,16,25 182:12 184:6 2:09 (1) 145:14	2:17-cv-2101 (1) 1:10 2:47 (1) 181:16 2:49 (1) 181:4 200 (1) 2:13 2000 (22) 13:11,13,19 56:25 57:11 58:9 59:7 93:7 100:18,21,23 101:4 102:3 111:22 113:16 115:12 116:2,17,21 118:8 166:4 167:4 2000/2001 (1) 44:10 2000s (1) 16:16 2001 (4) 41:10 44:12,14 45:7 2003 (6) 37:19 38:7 40:20 41:6 41:17 147:13 2004 (2) 150:23 151:3 2004/2005 (2) 150:13 151:7 2005 (3) 93:22 150:24 151:4 2012 (1) 165:7 2013 (7) 97:25 98:23 108:12 113:18 134:17 144:5 163:22 2014 (4) 108:12 113:18 138:3 138:16 2015 (10) 29:20 36:6 37:6,13,19 38:7 95:22 132:11 140:10,17 2016 (29) 13:4,22 46:11 56:25 57:11,14 58:9 59:8 69:13 75:14 76:23 77:4 78:14 93:17 96:5,17 99:8 100:18 100:24 101:4 120:16 121:23 122:12 123:5,7 132:11 141:3 166:4 168:25 2017 (4)	34:23 66:13 132:11 141:5 2018 (29) 1:12 7:16 8:2,20,25 10:20 22:22 23:8,21 24:4,13,18,24 25:2 25:7,19,19 26:7,19 27:5,13,25 87:10 141:4,5 182:14 183:8,10 185:23 21 (1) 121:9 217-CV-2101 (1) 3:10 22 (4) 69:24 70:24 134:18 135:16 23 (3) 135:2,17 182:14 23rd (7) 24:4,13,18,24 25:14 25:18 29:20 24-hour (2) 106:2,7 25 (3) 59:23 119:2 166:11 25th (1) 10:20 26 (1) 6:19 26.825 (1) 69:16 27 (1) 144:5 28 (1) 182:15 <hr/> 3 <hr/> 3 (4) 10:12,15 182:13 184:7 3.0 (1) 73:17 3.1 (3) 72:24 73:13,16 3.2 (1) 73:16 30 (2) 140:21 141:10 30305 (1) 2:15 30XI00235100 (1) 1:20 31 (1) 182:14 31st (14)
---	--	--	--	---

<p>7:16 8:2,20,25 10:7 22:22 23:8 25:14,19 26:7,19 27:5,13,25</p> <p>333 (1) 2:14</p> <p>35 (2) 42:7 108:11</p> <p>395 (2) 35:8,17</p> <hr/> <p>4</p> <hr/> <p>4 (3) 22:20 23:2 182:14</p> <p>4,175,180 (1) 182:5</p> <p>40 (1) 5:2</p> <p>495 (1) 35:10</p> <hr/> <p>5</p> <hr/> <p>5 (3) 28:6,9 182:15</p> <p>50 (1) 136:13</p> <p>510(k) (5) 46:24 48:13 62:7,12 64:12</p> <p>523 (6) 18:6,8 61:25 65:6 114:11 125:15</p> <p>57 (5) 124:2,4 125:14 126:3 127:8</p> <p>58 (3) 125:14 126:3 127:8</p> <hr/> <p>6</p> <hr/> <p>6 (5) 120:8,12 123:14 182:10,16</p> <p>60 (1) 41:24</p> <p>60/40 (1) 41:23</p> <p>65 (1) 42:6</p> <hr/> <p>7</p> <hr/> <p>7 (9) 141:19,24 142:9,12 142:18 143:6,9 163:22 182:17</p> <p>7.75 (3) 25:21,24 26:6</p> <p>7/31/2018 (1)</p>	<p>26:15</p> <p>750 (2) 108:14 110:7</p> <hr/> <p>8</p> <hr/> <p>8 (9) 2:5 141:21,25 142:9 142:13 143:7,11,16 182:19</p> <hr/> <p>9</p> <hr/> <p>9 (1) 182:12</p> <p>9/14/18 (1) 3:13</p> <p>90 (4) 38:8 108:9 110:3,7</p> <p>90s (2) 16:15 151:14</p> <p>95 (6) 36:25 37:7,7 38:8 40:14 151:7</p> <p>97 (1) 44:12</p>			
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